UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	

NOTICE OF FILING

On October 5, 2006, defendant Richard F. Selden ("Dr. Selden") initiated a civil action in this Court captioned Richard F. Selden v. United States Food and Drug Administration, et al., Civ. No. 06-11807-NMG (D. Mass.) ("FDA Action"), seeking declaratory and injunctive relief against the United States Food and Drug Administration ("FDA") and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA, to obtain the FDA's meaningful compliance with a final ruling of the United States District Court for the District of Columbia in S.E.C. v. Richard F. Selden, Misc. Case No. 1:05-mc-00476-RMU (D.D.C., Aug. 16, 2006), granting Dr. Selden's motion to compel and ordering the FDA to produce documents in response to two federal subpoenas issued by Dr. Selden on October 28, 2005.

Attached hereto is a copy of all papers filed by Dr. Selden on October 5, 2006 in the FDA Action, with an index provided below:

Exhibit 1	Complaint
Exhibit 2	Motion For Order To Show Cause And Preliminary Injunction

Exhibit 3	Plaintiff's Memorandum Of Law In Support Of His Motion For Order To Show Cause And Preliminary Injunction
Exhibit 4	Affidavit Of Justin J. Daniels In Support Of Plaintiff's Motion For Order To Show Cause And Preliminary Injunction
Exhibit 5	Plaintiff's Statement Concerning The Court's Jurisdiction In This Matter
Exhibit 6	Notice Of Filing With Clerk's Office

Dated: October 27, 2006
Boston, Massachusetts

Respectfully submitted,

/s/ Justin J. Daniels

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CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on October 27, 2006.

Dated: October 27, 2006

/s/ Justin J. Daniels
Justin J. Daniels

EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No.
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	Related To: S.E.C. v. Richard F. Selden, Civil Action No. 05-11805-NMG
Defendants.	:	

06 CA 11807 NMG

COMPLAINT

Plaintiff Richard F. Selden ("Dr. Selden"), by his undersigned attorneys, brings this action for declaratory and injunctive relief against the United States Food and Drug Administration ("FDA") and Andrew C. Von Eschenbach, in his official capacity as acting commissioner of the FDA (collectively, "Defendants"), pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-06, the Mandamus Act, 28 U.S.C. § 1361, the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, and for his Complaint alleges, upon knowledge with respect to himself and his own acts, and upon information and belief with respect to all other matters, as follows:

Nature Of The Action

1. This action seeks declaratory and injunctive relief against Defendants to require the FDA's meaningful compliance with the final ruling of the United States District Court for the District of Columbia ("D.C. Court") in S.E.C. v.

Richard F. Selden, No. 1:05-mc-00476-RMU (D.D.C., Aug. 16, 2006) (the "D.C. Order"), attached hereto as Exhibit A, granting Dr. Selden's motion to compel and ordering the FDA to produce documents in response to two federal subpoenas issued by Dr. Selden on October 28, 2005 (the "Subpoenas"). Although the parties have agreed on the scope of the production, the FDA now says it will take twenty-two months to perform the ministerial task of actually providing the documents.

2. The FDA's refusal to comply with the D.C. Order within a reasonable time frame is, under the circumstances, a refusal to comply with the D.C. Order altogether, and thus constitutes improper, illegal and prohibited agency action. Further, if allowed, the FDA's schedule will effectively eviscerate the D.C. Order and irreparably harm Dr. Selden. Dr. Selden therefore seeks an order requiring the FDA to comply in a meaningful way with the D.C. Order and to provide all agreed documents within a reasonable time frame and, in any event, by no later than November 15, 2006.

Parties

3. Plaintiff Richard F. Selden resides in Wellesley, Massachusetts. Dr. Selden is the founder and former President and Chief Executive Officer of Transkaryotic Therapies, Inc. ("TKT"), a small biotechnology firm previously located in Cambridge, Massachusetts. TKT has since been sold to a large pharmaceutical company in the United Kingdom.

4. Defendant FDA is a federal administrative agency within the Department of Health and Human Services.

5. Defendant Andrew C. von Eschenbach is the acting commissioner of the FDA and is sued in his official capacity as head of that agency.

Jurisdiction

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1361 and 1651, and 5 U.S.C. § 552(a)(4)(B).

7. Venue lies in this District pursuant to 28 U.S.C. § 1391(e) and 5 U.S.C. § 552(a)(4)(B), because Dr. Selden resides in this District, and also lies pursuant to 28 U.S.C. § 1391(e), because a substantial part of the events or omissions giving rise to the claims occurred in this District.

The Need For Expedited Treatment

8. Upon a showing of good cause, the District Court can grant expedited consideration of this action. 28 U.S.C. § 1657. For the reasons set forth below, Dr. Selden respectfully submits that good cause exists for this Court to grant expedited consideration of this action.

Facts

9. Dr. Selden is the defendant in a securities enforcement action brought by the U.S. Securities and Exchange Commission ("SEC") in this Court. S.E.C. v. Richard F. Selden, No. 05-11805-NMG (D. Mass., filed Sept. 1, 2005) (the "SEC Action").

10. The SEC alleges that Dr. Selden violated the federal securities laws in connection with the FDA's review for domestic marketing approval of Replagal, TKT's drug for the treatment of Fabry disease, a rare genetic disorder. According to the SEC's Complaint, Dr. Selden, in his position as CEO of TKT, is responsible for a "series of [allegedly] materially misleading public statements by TKT about the status of the FDA application for Replagal." Complaint, S.E.C. v. Selden, Docket No. 1 ("SEC Compl."), ¶ 1.

11. The SEC's entire case is based on the FDA's review of TKT's application for Replagal, its communications with TKT in this regard, and the steps both the FDA and TKT perceived as necessary for Replagal to obtain marketing approval in the United States. See, e.g., SEC Compl. ¶¶ 2-4, 12-14, 21-22, 24-26, 28-33, 35, 38-39, 41-42, 44-53, 55, 59-60, 62, 66, 70 & 74.

12. In addition to its close substantive connection to this case, the FDA has also actively assisted the SEC in its effort to collect information leading to this lawsuit. Among other things, the FDA provided documents to the SEC within weeks of request, made FDA staff available for "off the record" interviews by SEC representatives, and received updates from the SEC concerning the progress of the investigation.

13. Given the critical importance of FDA evidence to Dr. Selden's defense, on October 28, 2005 -- the first day he was permitted to do so by the Federal Rules of Civil Procedure -- Dr. Selden issued two federal subpoenas on the FDA going directly to the issues raised by the SEC's Complaint.

14. In addition to satisfying Rule 45 of the Federal Rules of Civil Procedure, the Subpoenas, under FDA regulations, constituted sufficient requests for agency records under FOIA. See 21 C.F.R. 20.2(a).

15. However, in contrast to the prompt assistance and cooperation the FDA provided to the SEC in response to the SEC's requests, with respect to Dr. Selden, the FDA put up roadblocks and delays at every turn, forcing him to move to compel FDA compliance with the Subpoenas in the D.C. Court.

16. On August 16, 2006, the D.C. Court granted in its entirety Dr. Selden's motion to compel FDA compliance with the Subpoenas and denied the FDA's motion to quash same. See Ex. A, attached hereto.

17. On August 25, 2006, the parties filed a Joint Status Report with the D.C. Court. The parties reported agreement on all but one category of documents the FDA would produce. However, the FDA also stated that it would take the agency twenty-two months to actually perform the ministerial task of collecting, reviewing and producing those documents; even though Dr. Selden had repeatedly informed the FDA that the only reason he is seeking the documents is to defend himself in the ongoing SEC Action. The FDA has nevertheless refused to change its twenty-two month schedule.

18. Dr. Selden now seeks injunctive and declaratory relief against Defendants to require the FDA to comply with its legal obligations and duties.

Irreparable Injury

19. The FDA's refusal to produce the documents in a timely manner will prevent Dr. Selden from being able to defend himself adequately and fairly in the SEC Action and thus will cause him irreparable injury for which there is no adequate remedy at law.

First Claim For Relief
(Administrative Procedure Act)

20. Dr. Selden repeats and restates the allegations contained in paragraphs 1 through 19 of his Complaint as if set forth fully herein.

21. The D.C. Order imposes a clear legal duty on Defendants.

22. The FDA's refusal to produce the required documents within a time frame such that they could be used for Dr. Selden's defense in the SEC Action, is a clear

breach of Defendants' legal duties under the D.C. Order and statutory law and constitutes final agency action for which there is no other adequate remedy in court.

23. Defendants' actions are arbitrary, capricious, an abuse of discretion and not in accordance with law.

24. Defendants have also withheld and unreasonably delayed agency action.

25. Dr. Selden has been adversely affected and aggrieved by Defendants' actions.

26. Dr. Selden has exhausted all available administrative remedies.

Second Claim For Relief
(Mandamus Act)

27. Dr. Selden repeats and restates the allegations contained in paragraphs 1 through 26 of his Complaint as if set forth fully herein.

28. Pursuant to the Mandamus Act: "The district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361.

29. The D.C. Order creates a clear, plainly prescribed, non-discretionary legal duty owed to Dr. Selden, requiring only ministerial acts to satisfy.

30. Dr. Selden has been adversely affected and aggrieved by Defendants' actions.

31. Dr. Selden's claim is clear and certain, seeking FDA compliance with the D.C. Order and the document production parameters filed as part of the Joint Status Report with the D.C. Court and this Court on August 25, 2006.

32. Dr. Selden has exhausted all available administrative remedies.

33. No other adequate remedy is available.

Third Claim For Relief
(Freedom Of Information Act)

34. Dr. Selden repeats and restates the allegations contained in paragraphs 1 through 33 of his Complaint as if set forth fully herein.

35. The FDA's failure to produce records in response to Dr. Selden's requests and the D.C. Order is subject to determination by this Court pursuant to the provisions of 5 U.S.C. § 552(a)(4)(B).

36. Dr. Selden has satisfied all requirements prescribed by statute and by FDA regulations for FOIA requests and appeals; and has satisfied all conditions precedent to the filing of a suit in this Court, including, but not limited to, exhaustion of his administrative remedies.

37. The records Dr. Selden requests were created or obtained by the FDA in the conduct of its agency functions; were in the FDA's possession, custody or control at the time Dr. Selden made his requests; and are currently within the FDA's possession, custody or control and, therefore, are "agency records" of the FDA within the meaning of 5 U.S.C. §§ 552(a)(3), (a)(4)(B), and (f)(2).

38. The records Dr. Selden seeks contain information critical to his defense in the SEC Action.

39. Defendants have improperly withheld these records.

40. Substantial and important rights of Dr. Selden -- including but not limited to his rights of access to the courts and to a fair trial -- are being unlawfully

curtailed by Defendants' failure to produce the records well enough in advance of the deadline for pretrial discovery in the SEC Action.

41. No other adequate remedy is available.

Fourth Claim For Relief
(Declaratory Judgment)

42. Dr. Selden repeats and restates the allegations contained in paragraphs 1 through 41 of his Complaint as if set forth fully herein.

43. Under the Declaratory Judgment Act, 28 U.S.C. § 2201, with respect to any "case of actual controversy within its jurisdiction," "any court of the United States, upon the filing of an appropriate pleading, may declare the rights and legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

44. Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.

45. A justiciable controversy exists with respect to Defendants' refusal to comply with the D.C. Order and in their failure to provide Dr. Selden in a meaningful manner with the court-ordered discovery.

46. Dr. Selden seeks a declaration pursuant to the Declaratory Judgment Act that Defendants' failure to provide him with adequate production constitutes a violation of, inter alia, the D.C. Order and APA § 552.

PRAYER FOR RELIEF

WHEREFORE, Dr. Selden respectfully requests that this Court:

a. Declare that withholding of the requested records and documents by Defendants is unlawful;

b. Order Defendants to promptly produce the requested records and documents to Dr. Selden;

c. Enjoin Defendants from withholding the requested records and documents;

d. Award Dr. Selden his attorneys' fees and costs of suit pursuant to 5 U.S.C. § 552(a)(4)(E); and

e. Grant such other and further relief as the Court deems just and equitable.

Dated: October 5, 2006
Boston, Massachusetts

Respectfully submitted,

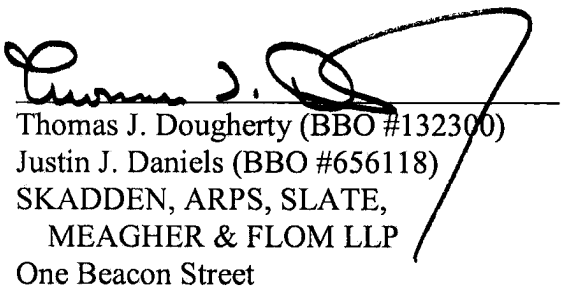

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

ORDER

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

For the reasons stated in the Memorandum Opinion contemporaneously filed herewith, it is this 16th day of August, 2006,

ORDERED that defendant Selden's motion to compel is **GRANTED**, and it is

FURTHER ORDERED that the FDA's motion to quash is **DENIED**, and it is

ORDERED that the FDA comply with Selden's subpoenas in accordance with the FDA's *Touhy* regulations, and it is

FURTHER ORDERED that the parties provide this court (and a courtesy copy to the trial court in Massachusetts) with a joint status report outlining the parties' anticipated timing for

the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations.

The parties must file their joint status report within 7 days of this order.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

MEMORANDUM OPINION

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

I. INTRODUCTION

The United States Securities and Exchange Commission ("SEC") filed a securities enforcement action against Richard F. Selden in federal court in Massachusetts. In preparing his defense, Selden served two subpoenas on the United States Food and Drug Administration and the Center for Biologics Evaluation and Review, a division of the Food and Drug Administration (collectively, the "FDA").

In the instant action, Selden seeks to compel the subpoenas *duces tecum* he served on the FDA. The FDA seeks to quash the subpoenas arguing that Selden failed to comply with the FDA's regulations governing requests for document production and that the subpoenas are

unduly burdensome. Because the FDA's regulations require it to treat subpoenas as requests for records, and because the FDA has not yet processed Selden's subpoenas in accordance with those regulations, the court compels the FDA's compliance with the subpoenas and denies the FDA's motion to quash. Because the FDA has not yet processed Selden's subpoenas, the court cannot assess whether any document production would be unduly burdensome.

II. BACKGROUND

A. Factual Background

On September 1, 2005, the SEC filed a securities enforcement action against Richard F. Selden in the United States District Court for the District of Massachusetts. *SEC v. Selden*, Civ. No. 05-11805 (D. Mass. Sept. 1, 2005); Mot. to Compel at 1. The SEC's complaint alleges that Selden, in his position as chief operating officer for Transkaryotic Therapies, Inc. ("TKT"), a small biotechnologies firm, interfered with the FDA's review of TKT's drug, Replagal, for domestic marketing approval.[1] Mot. to Compel at 1. Specifically, the SEC alleges that Selden made "materially misleading public statements by TKT about the status of the FDA application for Replagal." Mot. to Compel, Ex. C ¶ 1.

To prepare his defense, Selden served two subpoenas on the FDA for testimony and

[1] Replagal is a TKT drug used for the treatment of Fabry disease, a rare genetic disorder caused by a missing enzyme needed to metabolize lipids in the body. Mot. to Compel at 1.

documents relating to Replagal, TKT, and Selden, or otherwise relating to the underlying case.[2] Mot. to Compel at 2; Mot. to Compel Ex. A-B; Mot. to Quash at 2-3. In a letter dated November 9, 2005, the FDA objected to the subpoenas and requested that Selden withdraw them.[3] Mot. to Compel Ex. D ("Objection Letter"). In numerous letter between the FDA and Selden, the FDA reiterated its objections to the subpoenas and encouraged Selden to file his request for documents pursuant to the Freedom of Information Act ("FOIA"). Mot. to Quash at 5-6. Selden did not withdraw the subpoenas but instead reasserted his need for the information in preparing his defense in the securities enforcement action in Massachusetts. Mot. to Compel at 2.

2. Procedural Background

On February 10, 2006, this court held the case in abeyance pending a ruling by the United States Court of Appeals for the District of Columbia in the case of *Yousuf v. Samantar*, 451 F.3d 248 (D.C. Cir. 2006). Order (Feb. 10, 2006). On June 16, 2006, the Court of Appeals issued its ruling and held that a government agency is a "person" under Rule 45 and, therefore, can be the target of a third-party subpoena. *Yousuf*, 451 F.3d 248. Following the Court of

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[2] The subpoenas for testimony are not at issue here. The FDA responded to Selden's request for testimony by allowing the deposition of Dr. Marc K. Walton and denying Selden's request for testimony from James Kaiser, Rafel Rieves, and Karen Weiss. Supplemental Mem. in Supp. of Mot. to Quash Ex. 2. Selden has not objected to the FDA's denial of his request for testimony.

[3] The FDA objects to the subpoenas on the grounds that (1) the FDA is not a "person" within the meaning of Rule 45 and therefore cannot be the subject of a third-party subpoena; (2) the subpoenas do not comply with the FDA's *Touhy* regulations; (3) the requested documents contain "trade secrets and confidential commercial information;" (4) the requested documents are "exempt from public disclosure by the deliberative process privilege and personal privacy regulations;" (5) the subpoenas do not give the FDA "a reasonable time to respond;" and (6) the subpoenas are "unduly burdensome and over broad because they [seek] documents that [are] more than 18 years old, and because they [seek] certain documents that are publicly available in electronic format on the internet." Mot. to Quash at 4-5; Mot. to Compel Ex. D ("Objection Letter").

Appeals' decision, the parties submitted supplemental memoranda to the court addressing the applicability of *Yousuf* to the present case. Supplemental Mem. in Supp. of Mot. to Compel ("Supp. Mem. to Compel"); Supp. Mem. in Support of Mot. to Quash ("Supp. Mem. to Quash").

In his supplemental memorandum, Selden again seeks the FDA's compliance with the subpoenas and asks the court to compel full disclosure by August 31, 2006, so that Selden can prepare his defense in the Massachusetts action.[4] *Id.* The FDA continues to object to the subpoenas on the grounds that (1) the subpoenas do not comply with the FDA's *Touhy* regulations governing information requests, and that (2) the FDA would be unduly burdened by compliance with the subpoenas.[5] Supp. Mem. to Quash, 6-11. The FDA, therefore, asks the court to quash the subpoenas or, in the alternative, to (1) narrow the scope of the subpoenas; (2) provide a "reasonable time period" for the FDA to respond; and/or (3) require Selden pay the costs of the requested production. *Id.* at 12-14. The court now turns to these claims.

III. ANALYSIS

1. Legal Standard for *Touhy* Regulations

A federal government agency may create procedures for responding to subpoenas and requests for testimony pursuant to 5 U.S.C. § 301, the federal "housekeeping" statute. *Bobreski v. EPA*, 284 F. Supp. 2d 67, 73 (D.D.C. 2003); *see also United States ex rel. Touhy v. Ragen*, 340

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[4] According to Selden, the parties in the Massachusetts action must complete all written discovery by October 30, 2006. Supp. Mem. to Compel, 8.

[5] Following the Court of Appeals' decision in *Yousuf*, the FDA has abandoned its claim that the government is not a "person" within the meaning of Rule 45. *See* Supp. Mot. to Quash, 1-2.

U.S. 462, 468 (1951). Specifically, § 301 authorizes the head of an agency to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use and preservation of its records, papers and property." *Bobreski*, 284 F. Supp. 2d at 73 (quoting 5 U.S.C. § 301). These regulations, generally called *Touhy* regulations, serve the government's need to make a "centraliz[ed] determination as to whether subpoenas duces tecum will be willingly obeyed or challenged[.]" *Touhy*, 340 U.S. at 468.

B. The Court Grants Selden's Motion to Compel and Denies the FDA's Motion to Quash the Subpoenas

The FDA maintains that Selden's subpoenas did not constitute valid requests for documents under the FDA's *Touhy* regulations. Mot. to Quash at 17-21; Supp. Mot. to Quash at 6-9. The FDA claims, therefore, that it is not required to respond to the subpoenas. *Id.*

Federal agencies must "follow their own rules, even gratuitous procedural rules that limit otherwise discretionary actions." *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003) (citing *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)). Under the FDA's own rules, "[a]ny request for records of the Food and Drug Administration, whether it be by letter *or by a subpoena duces tecum* or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part[.]" 21 C.F.R. § 20.2(a) (emphasis added). Under Subpart B, the FDA handles subpoenas *duces tecum* in accordance with the procedures for the production of all agency records pursuant to FOIA. 21 C.F.R. § 20.2(b).

Holding the FDA to its own rules then, the FDA must treat the subpoenas as requests for documents pursuant to its *Touhy* regulations and respond in kind. *Id.*; *see also* Supp. Mem. to

Quash Ex. 3 (Apr. 6, 2006 Selden Letter) (identifying the FDA's own regulations as requiring subpoenas to be treated as *Touhy* requests). And because the FDA must treat the subpoenas *duces tecum* as requests for documents under its *Touhy* regulations, the FDA must respond to Selden's subpoenas pursuant to its *Touhy* regulations.[6] Accordingly, the court grants Selden's motion to compel and denies the FDA's motion to quash the subpoenas.

C. The Court Declines to Rule on Whether the Subpoenas are Unduly Burdensome

The FDA must submit the subpoenas to its *Touhy* process pursuant to the court's ruling. The FDA argues, however, that compliance with the subpoenas would be unduly burdensome. But, because the agency has not yet taken the appropriate administrative action on these requests under its regulations, the extent of any document production pursuant to Selden's request is, at this juncture, speculative. The court, therefore, is unable to assess the FDA's argument that compliance would be burdensome. Accordingly, the court declines to rule on the FDA's objection that the subpoenas are unduly burdensome, declines to rule on the FDA's motion to modify the subpoenas, and orders the FDA to proceed under the policies it has set forth in its

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[6] Relying on the Court of Appeals' decision in *Yousuf*, Selden contends that he is entitled to immediate access to the documents; that he need not wait on the FDA's *Touhy* process. Supp. Mem. to Compel at 6-7. In *Yousuf*, the D.C. Circuit held that a government agency could be the subject of a third-party subpoena under Rule 45 of the Federal Rules of Civil Procedure. 451 F.3d at 250. Selden reads this decision as allowing a litigant, in subpoenaing a government agency, to bypass that agency's *Touhy* process altogether. Supp. Mem. to Compel at 6-7. Selden misapprehends the Court of Appeals' decision. In *Yousuf*, the court did not suggest that a litigant would be able to bypass a federal agency's *Touhy* regulations by subpoenaing the agency. In fact, the court explicitly acknowledged the role of *Touhy* regulations as the vehicle through which a federal agency responds to a subpoena *duces tecum*. *Yousuf*, 451 F.3d at 257 (citing *Touhy*, 340 U.S. at 464, 469). Accordingly, Selden must wait for the FDA to process his subpoenas under its *Touhy* regulations.

Touhy regulations.[7]

IV. CONCLUSION

For the foregoing reasons the court, this 16th day of August, 2006, compels the FDA's compliance with Selden's subpoenas in accordance with the FDA's *Touhy* regulations. An order instructing the parties in a manner consistent with this Memorandum Opinion is issued contemporaneously.

RICARDO M. URBINA
United States District Judge

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[7] The court notes that the FDA must proceed through its *Touhy* process prior to any document production and that, under its procedures, it will treat the subpoenas as FOIA requests. 21 C.F.R. § 20. The FDA indicates that the parties have made "significant progress" in negotiating the scope of Selden's document requests and that Selden has already received approximately 300 pages of responsive documents from the FDA. Supp. Mem. to Quash at 4-5. Selden contends that, although engaging in dialogue, the FDA has not produced any documents in response to his subpoenas. Supp. Mem. to Compel, 8.

Though delay will not affect this court's docket, the court reminds the FDA that Selden wants these documents to prepare a defense to the pending action in the United States District Court for the District of Massachusetts. Thus, the FDA must engage Selden's request, and formulate a response, with dispatch (rather than place Selden's subpoena request at the back of the FOIA que). Toward that end, the court orders the parties to provide this court and the trial court in Massachusetts with a joint status report outlining the parties' anticipated timing for the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The court anticipates and expects the FDA's good faith, prompt, and satisfactory compliance in this endeavor.

EXHIBIT 2

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No.
v.	:	06 CA 11807 NMG
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	Related To: S.E.C. v. Richard F. Selden, Civil Action No. 05-11805-NMG
Defendants.	:	**ORAL ARGUMENT REQUESTED ON MOTION FOR PRELIMINARY INJUNCTION**

MOTION FOR ORDER TO SHOW CAUSE AND PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure and the Local Rules of this Court, plaintiff Richard F. Selden ("Dr. Selden") hereby respectfully moves this Court for an Order To Show Cause requiring defendants the United States Food and Drug Administration ("FDA") and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA, to appear for hearing on the question of why a preliminary injunction should not issue requiring FDA compliance, by no later than November 15, 2006, with:

(1) the August 16, 2006 Order of the United States District Court for the District of Columbia in S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C.) (attached hereto at Tab A), granting in its entirety Dr. Selden's motion to compel the FDA's compliance with two federal subpoenas issued on October 28, 2005 (the "D.C. Order");

(2) the agreed upon schedule of documents submitted to this Court and the D.C. Court on August 25, 2006 (attached hereto at Tab B); and

(3) any additional obligations imposed by law in connection with any document production, including, but not limited to, the Freedom of Information Act ("FOIA").

The grounds for this motion are set forth in the above-referenced documents, and in Dr. Selden's other supporting papers, respectfully submitted herewith.

REQUEST FOR ORAL ARGUMENT

Pursuant to Local Rule 7.1(D), Plaintiff requests oral argument on the motion for preliminary injunction, notice of which shall be issued by way of Order To Show Cause in a form substantially similar to that attached hereto at Tab C.

CERTIFICATION UNDER LOCAL RULE 7.1(A)(2)

The undersigned hereby certifies that counsel for Plaintiff conferred with opposing counsel regarding the filing of this motion.

Dated: October 5, 2006

Justin J. Daniels

Dated: October 5, 2006
Boston, Massachusetts

Respectfully submitted,

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION, Plaintiff, v. RICHARD F. SELDEN, Defendant, and, FOOD AND DRUG ADMINISTRATION, Interested Party.	Misc. No.:	05-0476 (RMU)
	Document No.:	1, 7

ORDER

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

For the reasons stated in the Memorandum Opinion contemporaneously filed herewith, it is this 16th day of August, 2006,

ORDERED that defendant Selden's motion to compel is **GRANTED**, and it is

FURTHER ORDERED that the FDA's motion to quash is **DENIED**, and it is

ORDERED that the FDA comply with Selden's subpoenas in accordance with the FDA's *Touhy* regulations, and it is

FURTHER ORDERED that the parties provide this court (and a courtesy copy to the trial court in Massachusetts) with a joint status report outlining the parties' anticipated timing for

the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The parties must file their joint status report within 7 days of this order.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

MEMORANDUM OPINION

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

I. INTRODUCTION

The United States Securities and Exchange Commission ("SEC") filed a securities enforcement action against Richard F. Selden in federal court in Massachusetts. In preparing his defense, Selden served two subpoenas on the United States Food and Drug Administration and the Center for Biologics Evaluation and Review, a division of the Food and Drug Administration (collectively, the "FDA").

In the instant action, Selden seeks to compel the subpoenas *duces tecum* he served on the FDA. The FDA seeks to quash the subpoenas arguing that Selden failed to comply with the FDA's regulations governing requests for document production and that the subpoenas are

unduly burdensome. Because the FDA's regulations require it to treat subpoenas as requests for records, and because the FDA has not yet processed Selden's subpoenas in accordance with those regulations, the court compels the FDA's compliance with the subpoenas and denies the FDA's motion to quash. Because the FDA has not yet processed Selden's subpoenas, the court cannot assess whether any document production would be unduly burdensome.

II. BACKGROUND

A. Factual Background

On September 1, 2005, the SEC filed a securities enforcement action against Richard F. Selden in the United States District Court for the District of Massachusetts. *SEC v. Selden*, Civ. No. 05-11805 (D. Mass. Sept. 1, 2005); Mot. to Compel at 1. The SEC's complaint alleges that Selden, in his position as chief operating officer for Transkaryotic Therapies, Inc. ("TKT"), a small biotechnologies firm, interfered with the FDA's review of TKT's drug, Replagal, for domestic marketing approval.[1] Mot. to Compel at 1. Specifically, the SEC alleges that Selden made "materially misleading public statements by TKT about the status of the FDA application for Replagal." Mot. to Compel, Ex. C ¶ 1.

To prepare his defense, Selden served two subpoenas on the FDA for testimony and

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[1] Replagal is a TKT drug used for the treatment of Fabry disease, a rare genetic disorder caused by a missing enzyme needed to metabolize lipids in the body. Mot. to Compel at 1.

documents relating to Replagal, TKT, and Selden, or otherwise relating to the underlying case.[2] Mot. to Compel at 2; Mot. to Compel Ex. A-B; Mot. to Quash at 2-3. In a letter dated November 9, 2005, the FDA objected to the subpoenas and requested that Selden withdraw them.[3] Mot. to Compel Ex. D ("Objection Letter"). In numerous letter between the FDA and Selden, the FDA reiterated its objections to the subpoenas and encouraged Selden to file his request for documents pursuant to the Freedom of Information Act ("FOIA"). Mot. to Quash at 5-6. Selden did not withdraw the subpoenas but instead reasserted his need for the information in preparing his defense in the securities enforcement action in Massachusetts. Mot. to Compel at 2.

2. Procedural Background

On February 10, 2006, this court held the case in abeyance pending a ruling by the United States Court of Appeals for the District of Columbia in the case of *Yousuf v. Samantar*, 451 F.3d 248 (D.C. Cir. 2006). Order (Feb. 10, 2006). On June 16, 2006, the Court of Appeals issued its ruling and held that a government agency is a "person" under Rule 45 and, therefore, can be the target of a third-party subpoena. *Yousuf*, 451 F.3d 248. Following the Court of

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[2] The subpoenas for testimony are not at issue here. The FDA responded to Selden's request for testimony by allowing the deposition of Dr. Marc K. Walton and denying Selden's request for testimony from James Kaiser, Rafel Rieves, and Karen Weiss. Supplemental Mem. in Supp. of Mot. to Quash Ex. 2. Selden has not objected to the FDA's denial of his request for testimony.

[3] The FDA objects to the subpoenas on the grounds that (1) the FDA is not a "person" within the meaning of Rule 45 and therefore cannot be the subject of a third-party subpoena; (2) the subpoenas do not comply with the FDA's *Touhy* regulations; (3) the requested documents contain "trade secrets and confidential commercial information;" (4) the requested documents are "exempt from public disclosure by the deliberative process privilege and personal privacy regulations;" (5) the subpoenas do not give the FDA "a reasonable time to respond;" and (6) the subpoenas are "unduly burdensome and over broad because they [seek] documents that [are] more than 18 years old, and because they [seek] certain documents that are publicly available in electronic format on the internet." Mot. to Quash at 4-5; Mot. to Compel Ex. D ("Objection Letter").

Appeals' decision, the parties submitted supplemental memoranda to the court addressing the applicability of *Yousuf* to the present case. Supplemental Mem. in Supp. of Mot. to Compel ("Supp. Mem. to Compel"); Supp. Mem. in Support of Mot. to Quash ("Supp. Mem. to Quash").

In his supplemental memorandum, Selden again seeks the FDA's compliance with the subpoenas and asks the court to compel full disclosure by August 31, 2006, so that Selden can prepare his defense in the Massachusetts action.[4] *Id.* The FDA continues to object to the subpoenas on the grounds that (1) the subpoenas do not comply with the FDA's *Touhy* regulations governing information requests, and that (2) the FDA would be unduly burdened by compliance with the subpoenas.[5] Supp. Mem. to Quash, 6-11. The FDA, therefore, asks the court to quash the subpoenas or, in the alternative, to (1) narrow the scope of the subpoenas; (2) provide a "reasonable time period" for the FDA to respond; and/or (3) require Selden pay the costs of the requested production. *Id.* at 12-14. The court now turns to these claims.

III. ANALYSIS

1. Legal Standard for *Touhy* Regulations

A federal government agency may create procedures for responding to subpoenas and requests for testimony pursuant to 5 U.S.C. § 301, the federal "housekeeping" statute. *Bobreski v. EPA*, 284 F. Supp. 2d 67, 73 (D.D.C. 2003); *see also United States ex rel. Touhy v. Ragen*, 340

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[4] According to Selden, the parties in the Massachusetts action must complete all written discovery by October 30, 2006. Supp. Mem. to Compel, 8.

[5] Following the Court of Appeals' decision in *Yousuf*, the FDA has abandoned its claim that the government is not a "person" within the meaning of Rule 45. *See* Supp. Mot. to Quash, 1-2.

U.S. 462, 468 (1951). Specifically, § 301 authorizes the head of an agency to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use and preservation of its records, papers and property." *Bobreski*, 284 F. Supp. 2d at 73 (quoting 5 U.S.C. § 301). These regulations, generally called *Touhy* regulations, serve the government's need to make a "centraliz[ed] determination as to whether subpoenas duces tecum will be willingly obeyed or challenged[.]" *Touhy*, 340 U.S. at 468.

B. The Court Grants Selden's Motion to Compel and Denies the FDA's Motion to Quash the Subpoenas

The FDA maintains that Selden's subpoenas did not constitute valid requests for documents under the FDA's *Touhy* regulations. Mot. to Quash at 17-21; Supp. Mot. to Quash at 6-9. The FDA claims, therefore, that it is not required to respond to the subpoenas. *Id.*

Federal agencies must "follow their own rules, even gratuitous procedural rules that limit otherwise discretionary actions." *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003) (citing *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)). Under the FDA's own rules, "[a]ny request for records of the Food and Drug Administration, whether it be by letter *or by a subpoena duces tecum* or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part[.]" 21 C.F.R. § 20.2(a) (emphasis added). Under Subpart B, the FDA handles subpoenas *duces tecum* in accordance with the procedures for the production of all agency records pursuant to FOIA. 21 C.F.R. § 20.2(b).

Holding the FDA to its own rules then, the FDA must treat the subpoenas as requests for documents pursuant to its *Touhy* regulations and respond in kind. *Id.*; *see also* Supp. Mem. to

Quash Ex. 3 (Apr. 6, 2006 Selden Letter) (identifying the FDA's own regulations as requiring subpoenas to be treated as *Touhy* requests). And because the FDA must treat the subpoenas *duces tecum* as requests for documents under its *Touhy* regulations, the FDA must respond to Selden's subpoenas pursuant to its *Touhy* regulations.[6] Accordingly, the court grants Selden's motion to compel and denies the FDA's motion to quash the subpoenas.

C. The Court Declines to Rule on Whether the Subpoenas are Unduly Burdensome

The FDA must submit the subpoenas to its *Touhy* process pursuant to the court's ruling. The FDA argues, however, that compliance with the subpoenas would be unduly burdensome. But, because the agency has not yet taken the appropriate administrative action on these requests under its regulations, the extent of any document production pursuant to Selden's request is, at this juncture, speculative. The court, therefore, is unable to assess the FDA's argument that compliance would be burdensome. Accordingly, the court declines to rule on the FDA's objection that the subpoenas are unduly burdensome, declines to rule on the FDA's motion to modify the subpoenas, and orders the FDA to proceed under the policies it has set forth in its

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[6] Relying on the Court of Appeals' decision in *Yousuf*, Selden contends that he is entitled to immediate access to the documents; that he need not wait on the FDA's *Touhy* process. Supp. Mem. to Compel at 6-7. In *Yousuf*, the D.C. Circuit held that a government agency could be the subject of a third-party subpoena under Rule 45 of the Federal Rules of Civil Procedure. 451 F.3d at 250. Selden reads this decision as allowing a litigant, in subpoenaing a government agency, to bypass that agency's *Touhy* process altogether. Supp. Mem. to Compel at 6-7. Selden misapprehends the Court of Appeals' decision. In *Yousuf*, the court did not suggest that a litigant would be able to bypass a federal agency's *Touhy* regulations by subpoenaing the agency. In fact, the court explicitly acknowledged the role of *Touhy* regulations as the vehicle through which a federal agency responds to a subpoena *duces tecum*. *Yousuf*, 451 F.3d at 257 (citing *Touhy*, 340 U.S. at 464, 469). Accordingly, Selden must wait for the FDA to process his subpoenas under its *Touhy* regulations.

Touhy regulations.[7]

IV. CONCLUSION

For the foregoing reasons the court, this 16th day of August, 2006, compels the FDA's compliance with Selden's subpoenas in accordance with the FDA's *Touhy* regulations. An order instructing the parties in a manner consistent with this Memorandum Opinion is issued contemporaneously.

RICARDO M. URBINA
United States District Judge

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[7] The court notes that the FDA must proceed through its *Touhy* process prior to any document production and that, under its procedures, it will treat the subpoenas as FOIA requests. 21 C.F.R. § 20. The FDA indicates that the parties have made "significant progress" in negotiating the scope of Selden's document requests and that Selden has already received approximately 300 pages of responsive documents from the FDA. Supp. Mem. to Quash at 4-5. Selden contends that, although engaging in dialogue, the FDA has not produced any documents in response to his subpoenas. Supp. Mem. to Compel, 8.

Though delay will not affect this court's docket, the court reminds the FDA that Selden wants these documents to prepare a defense to the pending action in the United States District Court for the District of Massachusetts. Thus, the FDA must engage Selden's request, and formulate a response, with dispatch (rather than place Selden's subpoena request at the back of the FOIA que). Toward that end, the court orders the parties to provide this court and the trial court in Massachusetts with a joint status report outlining the parties' anticipated timing for the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The court anticipates and expects the FDA's good faith, prompt, and satisfactory compliance in this endeavor.

EXHIBIT B

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
1. All FDA documents relating to FDA's consideration of surrogate endpoints for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, including, but not limited to, all: A) internal FDA correspondence and documents relating to Dr. Selden, TKT, Replagal, the Fabrazyme Biologic License Application ("BLA"), or any Fabrazyme-related Investigational New Drug Application ("IND"); and B) materials from the Jan. 2003 FDA advisory committee meeting relating to Replagal or Fabrazyme. FDA will not produce: - documents submitted by TKT - Fabrazyme documents relating exclusively to chemistry, manufacturing, or controls ("CMC") - Fabrazyme documents generated after 4/23/03	A) FDA has an estimated 15,375 pages of potentially responsive documents, requiring 768 hours of review time. Anticipated production date uncertain.[2] B) FDA has an estimated 3,500 pages of potentially responsive documents, requiring 175 hours of review time. Anticipated production date uncertain.
2. All FDA documents relating to FDA's consideration of dual approval for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 4, 6, and 7.	See timing for Schedule A request 1.
3. Every complete response letter ("CRL") issued by the FDA's Center For Biologics Evaluation And Review ("CBER") from 1987 to the present.	**Open Issue, see Ex. B infra.**	If this request is narrowed to include every CRL issued by CBER in 2000 and 2001, subject to the criteria listed below in Exhibit B, FDA has identified 30 CRLs responsive to this request, totaling an estimated 393 pages and requiring 20 hours of review time. Anticipated production date of 10/3/06.
4. All documents relating to Replagal.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 6, and 7.	See timing for Schedule A request 1.
5. All documents relating to TKT but not to Replagal.	No production necessary.	N/A

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
6. All documents relating to Dr. Selden.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 4, and 7.	See timing for Schedule A request 1.
7. All documents relating to Fabrazyme through 4/24/03.	FDA will produce all: A) CRLs sent to Genzyme regarding Fabrazyme; B) Genzyme responses to Fabrazyme CRLs, except portions relating exclusively to CMC; C) correspondence between Genzyme and FDA, in addition to CRLs and CRL responses, relating to Fabrazyme; D) portions of the original Fabrazyme BLA or any Fabrazyme-related IND relating to clinical, safety, efficacy and/or clinical trials; E) internal FDA correspondence and documents relating to the Fabrazyme BLA or any Fabrazyme-related IND, except documents generated after 4/23/03; and F) materials from the Jan. 2003 FDA advisory committee meeting relating to Fabrazyme, except the meeting transcript and materials submitted by TKT.	A) FDA has already identified an estimated 25 pages of responsive documents, requiring 1.25 hours of review time. Anticipated production date of 9/29/06. B) FDA has an estimated 75 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 7,500 to 37,500 pages) of potentially responsive documents, requiring between 375 and 1,875 hours of review time. Anticipated production date uncertain. C) Anticipated production date of 12/31/06. D) FDA has an estimated 46 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 4,600 to 23,000 pages) of potentially responsive documents, requiring between 230 and 1,150 hours of review time. This estimate does not include any documents from any Fabrazyme-related INDs, which may contain even more potentially responsive documents. Anticipated production date uncertain. E) See timing for Schedule A request 1. F) See timing for Schedule A request 1.
8. All documents relating to the SEC lawsuit or any other actual/possible lawsuit involving TKT or Replagal.	FDA will produce all responsive documents, except: - documents submitted by TKT - documents unrelated to Replagal	FDA has an estimated 500 pages of potentially responsive documents. Anticipated production date of 12/31/06.

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
9. All guidelines for CBER review of BLAs, INDs, trials, protocols, etc.	FDA will produce any internal FDA manuals, guidelines or templates available for reference or use, as of January 1, 1996 or later, in connection with the review of a BLA or IND.	FDA has an estimated 41,000 pages of responsive documents, requiring 2050 hours of review time. Anticipated production date uncertain.
10. Record retention schedules under 21 C.F.R. § 20.23(c)	FDA will produce its Headquarters Record Control Schedule, last updated on 12/31/89, which FDA represents was the applicable record retention schedule for the period 1990 to present.	FDA has already collected 104 pages of responsive documents. Anticipated production date of 9/1/06.
11. All documents relating to the dissolution/potential dissolution of CBER.	No production necessary.	N/A
12. Any proposed or final documents relating to guiding public disclosure of BLA status.	FDA will produce any internal FDA proposals or draft guidelines relating to the public disclosure, by the applicant, of the status of the applicant's BLA.	FDA's preliminary search has not identified any documents responsive to this request.
13. All documents relating to joint FDA/SEC coordination.	FDA will produce all correspondence and communications, and all documents reflecting, memorializing or referring to any correspondence or communications, between FDA and the SEC relating to Dr. Selden, TKT, Replagal, or any joint FDA/SEC efforts to enhance inter-agency cooperation.	In addition to those documents identified as responsive to Schedule A Request 8, FDA has an estimated additional 1000 pages of potentially responsive documents. Anticipated production date of 12/31/06.

[1] Productions will be made by four different components within FDA on a rolling basis, and the anticipated production date is the final date by which the production of this category of documents will be completed by all FDA components. Estimates of the number of FDA staff hours necessary for production are based on an estimated 3 minutes per page for review and redaction of documents. FDA will provide a privilege log no later than 90 days after the completion of the production of each category of documents described above.

[2] See Exhibit B, Open Issue 1.

Exhibit B

Issue #1: Timing of FDA production of documents

FDA's position:

FDA is unable to provide the Court with an exact date for its completion of production of all documents responsive to Subpoena Requests 1, 2, 4, 6, 7(B), (D)-(F), and 13 because FDA's initial search has identified an estimated 120,375 pages of documents that are potentially responsive to these requests. Presently, FDA estimates that it will take two months to collect and organize these documents and twenty months to complete the review, redaction, and supervisory review of the redactions (assuming three full-time employees are assigned to work on this project for six to eight hours per day, and spend approximately 3 minutes per page for review and redaction). Thus, based on an estimated volume of up to 120,375 pages of documents, the total time to production is expected to be twenty-two months from the day the search begins. FDA will make every effort to adhere to this timeframe. If less than 120,375 pages of documents are ultimately identified, or if Dr. Selden is able to further refine his request as outlined below, the review and redaction times can be reduced proportionately (e.g., if only 71,975 pages are identified, the time to production could be reduced to about thirteen months). If more than 120,375 pages are ultimately identified, the review and redaction times would be increased (e.g., if 140,000 pages are identified, the time to production would increase to twenty-seven months).

With respect to Subpoena Request 7(B), FDA has immediately available the three CRLs that FDA sent to Genzyme relating to its Fabrazyme product, as well as the table of contents for Genzyme's responses to these three CRLs. With respect to Subpoena Request 7(D), FDA has immediately available the table of contents for the portions of the original BLA for Fabrazyme that relate to clinical safety and efficacy, as well as a Genzyme-prepared overview of the clinical safety and efficacy portion of the original BLA for Fabrazyme. In the interest of prioritizing the

Exhibit B

FDA resources that must be marshaled to produce documents pursuant to this request, FDA proposes to provide Dr. Selden with these tables of contents and overviews so that Dr. Selden can identify the order of priority for production of the documents that are responsive to this request. If Dr. Selden is willing to narrow his request using these materials, the time required by FDA for the production of the documents he seeks could be significantly reduced.

Dr. Selden's Position:

The Court in the District of Massachusetts has already extended the pre-trial calendar in SEC v. Selden by six months to accommodate FDA's delay in responding to the subpoenas. The current schedule now requires all written discovery to be completed by October 30, 2006, with all depositions to be completed by end of February 2007. Nevertheless, the FDA now says that it will need another 22 months -- or until the middle of 2008 -- to complete the production. Surely this could not be the "prompt" FDA response that the Court had in mind when granting Dr. Selden's motion to compel (see Memorandum Opinion, Docket Entry No. 19 at 7 n.7), given that it would render the subpoenas essentially meaningless. Further, it would deny Dr. Selden a fair defense against a government enforcement action brought with the assistance of FDA itself. Lastly, FDA's proposed 22-month schedule is not defensible because it does not jibe with the realities of litigation document review. For example, under FDA's estimate, it will take six weeks for one person to review and process a single box of documents.[3] Even a conservative estimate of the review time for a box of documents in a complex litigation would be no more than 4-5 days per box, a period that can be accelerated with additional resource commitment or,

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[3] This figure is derived as follows: The FDA estimates a total production of 120,375 pages of documents. One standard size file box (or "banker's box") can hold approximately 2,500-3,000 pages of documents. FDA says it will take three people 22 months to complete this production, meaning that one person will need 22 months to complete approximately 13-16 boxes, or 6-7 weeks per box, per person.

Exhibit B

specific to FDA, a waiver of the deliberative process privilege (see Issue #3, below). Thus, the Court should order FDA to comply with the subpoenas on an accelerated basis by October 30, 2006, the end of the written discovery period in SEC v. Selden.

Issue #2: Request No. 3[4]

(A) Time range for CRLs to be produced

FDA's position:

FDA has agreed to produce every CRL issued by CBER between January 1, 2000 and December 31, 2001, excluding those CRLs issued for products that were never approved, those CRLs sent in response to Biologic License Application ("BLA") supplements rather than original applications, and those CRLs issued for products for which user fees were not collected. Applying these criteria to narrow Dr. Selden's request ensures that only CRLs issued for products with applications that are similar to Replagal's application will be produced. The January 1, 2000 and December 31, 2001 time period proposed by FDA will result in the production of all such CRLs for the year proceeding and the year following FDA's issuance of the Replagal CRL, which was issued in January 2001.

FDA has identified 30 CRLs for products fitting the above criteria that were issued during the relevant two-year time period. This search required twelve hours of FDA staff time, the review and redaction of these CRLs will require an additional 20 hours, and production

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[4] Request No. 3 of Schedule A calls for "[e]very complete response letter ('CRL') issued by the FDA's Center For Biologics Evaluation And Review ('CBER') from 1987 to the present." The SEC v. Selden case concerns the Complete Response Letter of Transkaryotic Therapies, Inc. ("TKT"). In that action, the SEC alleges Dr. Selden fraudulently misrepresented what the CRL said and meant. Complete Response Letters (sometimes referred to as "Complete Review Letters" or "CRLs") are "issued [by CBER] when the complete review indicates that there are deficiencies remaining that preclude the approval of the application or supplement at that time. The Complete Response Letter will: Summarize all of the deficiencies remaining, and [w]here appropriate, describe actions necessary to place the application/supplement in a condition for approval." CBER Manual Of Standard Operating Procedures And Policies ("SOPP") 8405, version #4 (eff. Sept. 20, 2004). The definition of CRL has also been revised several times during the relevant period.

Exhibit B

should be complete by 10/3/06. If FDA were ordered to produce every CRL issued by CBER during the 18-year period sought by Dr. Selden, the resulting massive undertaking would require years of FDA staff time to search for, organize, review, redact, and produce the estimated 400,000 pages of responsive documents. As FDA has consistently maintained, such a request is "unduly burdensome and over broad" because it seeks documents "more than 18 years old," encompasses "many thousands of pages," and would thus "further strain FDA's already overburdened document production capacity." FDA Motion to Quash at 4, 8.

Dr. Selden's Position:

FDA's refusal to produce CRLs beyond the years 2000 and 2001 is a new position that FDA took only in the last three weeks. Nevertheless, Dr. Selden is willing to agree to a protocol that would make the production non-burdensome on FDA (see 2.B., below), but FDA has not been willing to discuss this option.

(B) Open issue regarding production of CRLs for unapproved products

FDA's position:

FDA may not produce any CRLs for products that have not been approved because its regulations forbid FDA from releasing any information regarding unapproved BLA's. See 21 C.F.R. § 601.51(b) ("The existence of a biological product file will not be disclosed by the Food and Drug Administration before a biologics license application has been approved unless it has previously been disclosed or acknowledged."). The very existence of a BLA for a product that has not yet received FDA approval may be considered trade secret and confidential commercial information ("CCI"), and FDA's release of such information could constitute a violation of both the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and the Federal Trade Secrets Act, 18 U.S.C. § 1905, both of which carry individual criminal liability. See Jerome Stevens Pharms.

Exhibit B

v. FDA, 319 F. Supp. 2d 45 (D.D.C. 2004), aff'd in part, rev'd in part, 420 F.3d 1249 (D.C. Cir. 2005) (seeking $1.345 billion in damages for FDA's alleged release of trade secret and CCI contained in a new drug application).

Neither of these statutes, nor FDA's regulations, provide for an "attorneys' eyes only" exception for the release of trade secret or CCI. Should the court order FDA to produce the CRLs that Dr. Selden seeks, FDA would need to alert the hundreds of entities to whom these unapproved CRLs were issued during this 18-year period to permit them to intervene in the present action to defend their proprietary information. See 21 C.F.R. § 20.48 (requiring FDA to give notice to "a person who will be affected by a proposed disclosure of data or information contained in Food and Drug records" to permit them "to institute suit in a United States District Court to enjoin release of the records" and prohibiting FDA from "disclos[ing] the records involved until the matter and all related appeals have been concluded").

Dr. Selden's Position:

FDA's stated position derives from a premise not at issue here; namely, that Dr. Selden is seeking the public disclosure of confidential information. Not so. Dr. Selden's interest in the materials is limited to defending himself in the government enforcement action; and FDA regulations specifically provide a process for limited disclosure of non-public information in connection with court proceedings:

> Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

Exhibit B

21 C.F.R. § 20.86 ("Disclosure in administrative or court proceedings") (emphasis added). Further, contrary to FDA's blanket assertion that it cannot produce any non-public information without an extensive notice period and the exhaustion of all legal remedies by those affected, FDA regulations contemplate production subject to measures that can be adopted "to reduce disclosure to the minimum necessary under the circumstances."

Consistent with the above, Dr. Selden is willing to agree to the entry of a protective order that would protect the confidentiality of the CRLs while permitting him limited use for purposes of his defense. However, to date FDA has refused to engage in any dialogue on what measures FDA believes are appropriate. Dr. Selden has already offered the following: first, Dr. Selden will agree to an order precluding the use of any non-public information outside of the SEC v. Selden litigation; second, Dr. Selden will agree to a protocol that limits CRL access to "attorneys' eyes only"; and third, Dr. Selden will agree that if information from the CRLs is referred to (by an expert, for example), such reference will not include the applicant name or product; but rather refer to a numerical identifier (e.g., "CRL #1").

Issue #3: FDA Assertion Of "Deliberative Process" Privilege Over Entire Production

FDA's position:

FDA is not intending to assert the deliberative process privilege over every document responsive to the subpoena. Indeed, Selden correctly asserts that FDA waived its deliberative process privilege with respect to a limited number of documents provided to the SEC in a completely unrelated matter, but the circumstances of that decision differed markedly from those in the present action. For instance, FDA disclosed the documents at issue in that case to the SEC pursuant to FDA regulations that permit the inter-agency sharing of documents. See 21 U.S.C. § 20.85.

Exhibit B

With respect to any assertion of the deliberative process privilege, FDA does not believe that this issue is ripe for decision at this point in the litigation. FDA will not agree to summarily waive the deliberative process privilege before the agency has had a chance to assert the privilege in regards to specific documents and provide the Court with the reasoning for the assertion on a privilege log. FDA believes, however, and has consistently maintained, that Dr. Selden's requests seek "disclosure of information that is or contains . . . pre-decisional, and/or agency deliberative process information that is protected from disclosure under the applicable laws, regulations, or privileges." See FDA November 9, 2005 Letter (Attached to Selden's Motion to Compel Memo as Attachment D). A consistent policy of withholding information subject to the deliberative process privilege encourages full and frank discussion among FDA decisionmakers. See 21 C.F.R. § 20.62 (permitting intra-agency writings to be withheld from public disclosure); see also Dep't of Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8-9 (2001) ("The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance 'the quality of agency decisions,' by protecting open and frank discussion among those who make them within the Government.").

Moreover, FDA's decision to withhold privileged information in the present litigation must be analyzed anew, within the confines of the present action. See In re Sealed Case, 121 F.3d 729, 737-738 (D.C. Cir. 1997) ("Each time the deliberative process privilege is asserted the district court must undertake a fresh balancing of the competing interests, taking into account factors such as the relevance of the evidence, the availability of other evidence, the seriousness of the litigation, the role of the government, and the possibility of future timidity by government employees.") (internal citation and quotation marks omitted). The Court's failure to perform a

Exhibit B

"fresh" review of FDA's assertion of the deliberative process privilege would not only negatively impact frank discussions among agency employees, but would also be a strong disincentive for the agency to ever agree to a waiver of the privilege, regardless of the circumstances. Because FDA has not to date asserted the deliberative process privilege in a concrete setting, the issue is not ripe for judicial consideration.

Dr. Selden's Position:

Until very recently, FDA stated that it was contemplating a waiver of the "deliberative process" privilege in this action as it did in the virtually identical SEC v. Biopure action. However, it now says it will not waive the privilege, but that it is premature to discuss its decision in court. FDA's denial of Dr. Selden's request is manifestly ripe for the Court's decision. For several reasons, FDA's decision is both arbitrary and unreasonable.

First, as recently as June 28, 2006, the FDA agreed to waive the privilege, in its entirety, in a virtually identical pending litigation in the District of Massachusetts also brought by the SEC and involving the same regulatory branch of FDA. See SEC v. Biopure Corp., et al., Civ. No. 05-11853-PBS (D. Mass., filed Sept. 15, 2005). There is no sound basis for denying Dr. Selden the same. For example, FDA's only stated reason for asserting the privilege in this case in contrast to Biopure is that the Biopure request came under 21 C.F.R. § 20.85, which provides for the inter-agency sharing of information. See FDA's Position, above. However, both FDA and the SEC have already agreed to use § 20.85 in this case, the same procedure used in Biopure, to request this information from FDA, thus rendering FDA's sole distinction non-existent.

Second, the FDA's only stated justification for asserting the privilege -- that it would "negatively impact frank discussions among agency employees" -- is inapplicable in this case

Exhibit B

because Dr. Selden is not seeking to disclose FDA information to the public, and is willing to agree to a protective order that expressly precludes it.

Third, the effect of the FDA's position would be to eviscerate perhaps the most important reason the subpoenas were issued in the first place; namely, to obtain an understanding of the FDA's own reactions and interpretations of its discussions with the company, Dr. Selden, and the product application.

Issue #4: Depositions of FDA employees

FDA's position:

The subpoenas served upon FDA by Dr. Selden in the present action also requested the depositional testimony of the FDA and the CBER records custodians. Dr. Selden has informed FDA that he seeks such testimony in order to authenticate the records produced by FDA pursuant to these subpoenas. In lieu of these depositions, FDA proposes to authenticate its records via Rule 902 of the Federal Rules of Evidence, consistent with FDA's standard practice when providing documents for use in third-party litigation. see 21 C.F.R. § 20.3 (providing for the certification and authentication of FDA records).

Dr. Selden now seeks to impermissibly expand the present action to encompass his demands for the testimony of four FDA scientists. Such testimony was requested by Dr. Selden pursuant to FDA's Touhy regulations in a letter dated March 29, 2006, See 21 C.F.R. § 20.1, well after the instant litigation was begun. Thus, this request is not part of the current case. After carefully considering this request, FDA permitted Dr. Selden to obtain the testimony of Dr. Walton, the FDA scientist who was previously deposed by the SEC. See FDA Letter dated June 30, 2006. FDA refused to grant Dr. Selden's request for the testimony of the three remaining

Exhibit B

scientists, citing, among other concerns, "FDA's limited resources and the vast number of requests the agency receives for its personnel to testify."

As this Court has already acknowledged, these "subpoenas for testimony are not at issue here." Memorandum Opinion, Aug. 16, 2006, p.3 n.2. FDA's response to Dr. Selden's request for testimony pursuant to FDA's Touhy regulations may only be challenged by Dr. Selden under an arbitrary and capricious standard of review in an action under the Administrative Procedure Act ("APA"). Far from being a "meaningless gesture" as Dr. Selden contends below, such a requirement is well established by the longstanding precedent of this Circuit. See Houston Bus. Journal, Inc. v. Office of the Comptroller, 86 F.3d 1208, 1212 n.4 (D.C. Cir. 1996) (directing third-party litigant to "proceed under the APA, and the federal court will review the agency's decision not to permit its employee to testify under an 'arbitrary and capricious' standard").

Dr. Selden's Position:

Referenced by the Court in its Aug. 16, 2006 Memorandum Opinion (see p. 3 n.2), the testimony of FDA employees Karen Weiss, Duane Rieves and James Kaiser -- which Dr. Selden requested pursuant to FDA's "Touhy" regulations -- are central to his defense and he objects to FDA's refusal to make them available.

The only stated basis for FDA's denial of the testimony is that it would be "duplicative" of Dr. Walton. (FDA's reference above to "other concerns" having been identified in the letter is misleading. The letter specifically stated that it was denying Dr. Selden's request on the basis of the supposed "duplicative" nature of the testimony.) FDA's position is demonstrably false, as Dr. Selden has already communicated to FDA.

Further, with respect to any burden on FDA, Dr. Selden is willing to conduct the depositions during off hours and at any location. A similar procedure was approved by the Court

Exhibit B

for FDA depositions in In re: Vioxx Products Liability Litig., No. MDL 1657, 2006 WL 784878, *12 (E.D. La. Mar. 15, 2006).

Finally, FDA's suggestion of Dr. Selden bringing a separate APA action for relief is, with all due respect, a meaningless gesture under these particular circumstances; where there is an ongoing enforcement action brought by the SEC with the assistance of FDA (including the FDA's permission of "off the record" interviews by SEC of several FDA employees), and is now heading for trial.

Issue #5: Payment of costs for production of FDA documents

FDA's position:

FDA intends to renew its request that Selden be responsible for the significant costs associated with responding to his voluminous subpoena requests, which FDA estimates will require it to dedicate thousands of staff hours in order to produce over 120,000 pages of responsive documents. See Fed. R. Civ. P. 45(c)(2)(B) ("[A]n order to compel production shall protect any person who is not a party . . . from significant expense resulting from the inspection and copying command."). In Northrop Corp. v. McDonnell Douglas Corp, the D.C. Circuit instructed courts to "fully recognize the burden of imposing on a non-party the effort and expense of discovery, particularly when the expense will be borne by the taxpayers." 751 F.2d 395, 407 (D.C. Cir. 1984); see also Linder v. Calero-Portocarrero, 251 F.3d 178, 182 (D.C. Cir. 2001) (concluding that "fee shifting was mandatory" under Rule 45 and requiring the requestor to bear all of the government's nearly $200,000 in costs).

If Dr. Selden's production was being conducted in response to a FOIA request rather than pursuant to a subpoena, the search and review charges would be $40.00 per hour for mid-grade employees, and duplication costs would be $0.10 per page based on the current fee schedule.

Exhibit B

See 21 C.F.R. § 20.45. Based on an estimated volume of up to 120,375 pages of documents and the assignment of three full-time, mid-grade employees for 6 hours per day for twenty-two months, the duplication costs would be approximately $12,000 and the search and review charges would be approximately $317,000.

Dr. Selden's Position:

Dr. Selden, a private citizen, is being accused of fraud by the federal government in an enforcement action that almost certainly would not have been brought without the assistance of FDA. The FDA's involvement in this case stems back to the earliest phases of the SEC's investigation. Having supplied critical assistance to the SEC, including "off the record" interviews of key witnesses, the FDA now wants Dr. Selden to bear the burden and expense of seeking discovery from the very agency that is behind the lawsuit against him. This is unfair and inappropriate.

EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No.
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	Related To: S.E.C. v. Richard F. Selden, Civil Action No. 05-11805-NMG
Defendants.	:	

[PROPOSED] ORDER TO SHOW CAUSE
REGARDING PRELIMINARY INJUNCTION

Upon the Complaint, Plaintiff's Motion For Order To Show Cause And Preliminary Injunction, Plaintiff's Memorandum Of Law In Support Of His Motion For Order To Show Cause And Preliminary Injunction, all other papers and proceedings herein, and good cause being shown:

IT IS HEREBY ORDERED THAT:

1. Defendants the United States Food and Drug Administration ("FDA") and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA, show cause before the Honorable Nathaniel M. Gorton, United States District Court Judge, in Courtroom #4 of the United States District Court for the District of Massachusetts, located at 1 Courthouse Way, Boston, Massachusetts at ___ __.m. on _____, 2006, or as soon thereafter as counsel can be heard, why a preliminary

and mandatory injunction pursuant to Fed. R. Civ. P. 65 should not be issued requiring the FDA to comply, by no later than November 15, 2006, with:

(a) the August 16, 2006 Order of the United States District Court for the District of Columbia in S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C.) (attached hereto at Tab A), granting in its entirety Dr. Selden's motion to compel the FDA's compliance with two federal subpoenas issued on October 28, 2005 (the "D.C. Order");

(b) the agreed upon schedule of documents submitted to this Court and the D.C. Court on August 25, 2006 (attached hereto at Tab B); and

(c) any additional obligations imposed by law in connection with any document production, including, but not limited to, the Freedom of Information Act ("FOIA").

2. Defendants' opposition papers, if any, shall be filed with the Clerk of this Court on or before Thursday, October 19, 2006; and Plaintiff's reply papers, if any, shall be filed with the Clerk of this Court on or before Thursday, October 26, 2006.

3. Plaintiff shall promptly serve a copy of this Order upon Defendants.

SO ORDERED.

Dated: _____, 2006

_____
, J.

EXHIBIT 3

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No.
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	Related To: S.E.C. v. Richard F. Selden, Civil Action No. 05-11805-NMG
Defendants.	:	06 CA 11807 NMG

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF HIS MOTION FOR ORDER TO SHOW CAUSE AND PRELIMINARY INJUNCTION

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Counsel for Plaintiff
Richard F. Selden

Dated: October 5, 2006

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Preliminary Statement

This action seeks declaratory and injunctive relief against the United States Food and Drug Administration ("FDA") and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA (collectively, "Defendants"), to obtain the FDA's meaningful compliance with a final ruling of the United States District Court for the District of Columbia ("D.C. Court") in S.E.C. v. Richard F. Selden, No. 1:05-mc-00476-RMU (D.D.C., Aug. 16, 2006) (the "D.C. Order"), granting Dr. Selden's motion to compel and ordering the FDA to produce documents in response to two federal subpoenas issued by Dr. Selden on October 28, 2005 (the "Subpoenas"). A copy of the D.C. Order is attached hereto at Tab A. Although the parties have already agreed on the scope of production, the FDA now says it will take the agency twenty-two months to perform the ministerial task of actually providing the documents. This delay period will effectively eviscerate the D.C. Order and irreparably harm Dr. Selden, who needs the discovery to defend himself in a government enforcement action pending before this Court.

Background

Dr. Selden respectfully refers to the background information provided in his Statement In Connection With The September 28, 2006 Status Conference, S.E.C. v. Richard F. Selden, No. 05-11805-NMG (D. Mass., filed Sept. 1, 2005) (the "SEC Action"), Docket No. 17, a copy of which is attached hereto at Tab B and to which Dr. Selden respectfully refers. Additional detail and materials are provided in the Affidavit Of Justin J. Daniels In Support Of Plaintiff's Motion For Order To Show Cause And Preliminary Injunction, filed today in connection with this motion.

Argument

I. THE COURT SHOULD ENTER A PRELIMINARY INJUNCTION REQUIRING THE FDA TO PRODUCE ALL COURT-ORDERED DOCUMENTS BY NOVEMBER 15, 2006

In determining whether to grant preliminary injunctive relief, the Court is to consider four factors: "(1) the likelihood of success on the merits; (2) the potential for irreparable harm if the injunction is denied; (3) the balance of relevant impositions, i.e., the hardship to the nonmovant if enjoined as contrasted with the hardship to the movant if no injunction issues; and (4) the effect (if any) of the court's ruling on the public interest." Ross-Simons Of Warwick, Inc. v. Baccarat, Inc., 102 F.3d 12, 15 (1st Cir. 1996); see also Thermo Web Sys., Inc. v. Beebe, No. 00-40170, 2000 WL 1876418, *2 (D. Mass. Dec. 20, 2000) (Gorton, J.). In addition, mandatory injunctions require the enjoined party to act affirmatively, "do not preserve the status quo and normally should be granted only in those circumstances when the exigencies of the situation demand such relief." Mass. Coal. Of Citizens With Disabilities v. Civil Def. Agency, 649 F.2d 71, 76 n.7 (1st Cir. 1981). Dr. Selden's motion meets and exceeds those standards.

A. Dr. Selden Has A Likelihood Of Success On The Merits Of His Claims For Relief

Dr. Selden asserts four meritorious causes of action against Defendants in support of his request for injunctive relief:

The APA Claim. The APA authorizes a reviewing court to "compel agency action unlawfully withheld or unreasonably delayed" and to "hold unlawful and set aside agency action, findings, and conclusions" that are, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

This is so even when the "agency action" at issue constitutes a failure to act. 5 U.S.C. § 551(13). Courts can also overturn an agency decision under the APA if the decision is "without observance of procedure required by law." Id. § 706(2)(D). In this case, Defendants' refusal to comply in a timely manner with the D.C. Order constitutes a clear withholding and unreasonable delay of agency action, as well as an unlawful failure to act.

The Mandamus Act Claim. Under the Mandamus Act, "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. For example, in Kahmann v. Reno, 967 F. Supp. 731 (N.D.N.Y. 1997), plaintiff claimed that the INS did not sufficiently comply with a prior district court order enforcing a "make whole" remedy imposed by the EEOC. Id. at 732. The Court granted the writ of mandamus and ordered additional agency compliance with the court order. Like Kahmann, the D.C. Order in this case creates a clear legal duty owed to Dr. Selden, and Defendants' twenty-two month schedule constitutes a plain violation of that Order in light of the pretrial schedule in the SEC Action. The mandamus claim is more than likely to succeed.

The FOIA Claim. Pursuant to 5 U.S.C. § 552(a)(4)(B), this Court may enjoin the FDA from withholding agency records and order the production of those records. The statute's basic purpose is "to ensure an informed citizenry, vital to the functioning of a democratic society, or, stated more specifically, to open agency action to the light of public scrutiny . . . The policy underlying FOIA is thus one of broad disclosure." Church of Scientology Int'l v. U.S. Dept. of Justice, 30 F.3d 224, 228 (1st Cir. 1994) (citations and internal quotations omitted). "Official information that sheds light on

an agency's performance of its statutory duties falls squarely within that statutory purpose." Globe Newspaper Co. v. F.B.I., No. 91-13257, 1992 WL 396327, *2 (D. Mass. Dec. 29, 1992) (Zobel, J.) (citations and internal quotations omitted). Here, the FDA effectively proposes no disclosure at all, since the only purpose for the disclosure in the first place was to permit Dr. Selden to mount a fair and complete defense to the government's enforcement action. If there is any case where enforcement of FOIA is vital, it is here.

The Declaratory Judgment Act Claim. For the reasons set forth above, Dr. Selden's Declaratory Act claim will also likely succeed on the merits.

B. Dr. Selden Will Suffer Irreparable Harm In The Absence Of This Injunction

The government in the SEC Action seeks, among other things, to bar Dr. Selden from ever serving as a director or officer of a public company and for a jury to attach a "fraud" label to his supposed actions. Now Dr. Selden faces the prospect of trying to defend himself without perhaps the most important discovery needed for his defense. The irreparable nature of this injury is palpable.

C. Dr. Selden's Irreparable Harm Far Outweighs Any Possible Discovery Burden On The FDA

Since the FDA has already agreed to produce the documents, the only remaining question is one of timing. Thus, the only "burden" on this $2 billion dollar-10,000 employee-federal agency is how to allocate its resources. This allocation issue pales in comparison to the harm to Dr. Selden caused by the denial of necessary discovery.

D. The Public Interest Will Be Served By Requiring FDA Compliance And By Protecting Dr. Selden's Right To A Fair Defense

The interests at stake for Dr. Selden are of deep public importance. Our entire modern civil process is meant to provide parties with fair access to, and complete disclosure of, all information relevant to the matter in dispute. A trial is not supposed to be a game of stonewall or blindman's bluff. U.S. v. Procter & Gamble Co., 356 U.S. 677, 683 (1958). It is a "search for the truth." 8 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 2001, at 40 (2d ed. 1994). Courts have long recognized that this search will succeed only if each and every party has the right to present its own evidence and to rebut that of its opponent. Indeed, it is a right that is "a fundamental element of due process of law." Washington v. Texas, 388 U.S. 14, 19 (1967); see also Westinghouse Elec. Corp. v. City of Burlington, 351 F.2d 762, 767 (D.C. Cir. 1965) ("[T]he paramount interest of the Government in having justice done between litigants in the Federal courts militates in favor of requiring a great effort on its part to produce any documents relevant to a fair termination of this litigation."). In this case, Defendants' refusal to produce documents in a timely manner cuts directly against this basic principle.

Conclusion

Dr. Selden's nearly year-long effort to obtain discovery from the FDA is continuing. Although the D.C. Court entered a final order granting his motion to compel, the FDA's self-created, twenty-two month production schedule threatens to undo any possible benefit from the Order. For all of those reasons, as well as the reasons contained in Dr. Selden's other supporting papers, this Court should grant Plaintiff's Motion For

Order To Show Cause And Preliminary Injunction and direct entry of an order consistent with the relief requested herein.

Dated: October 5, 2006
Boston, Massachusetts

Respectfully submitted,

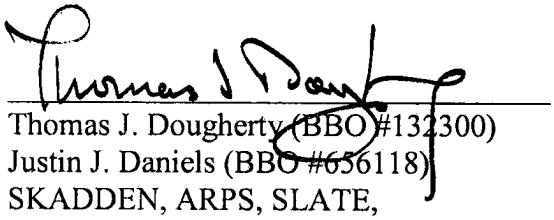

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

ORDER

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

For the reasons stated in the Memorandum Opinion contemporaneously filed herewith, it is this 16th day of August, 2006,

ORDERED that defendant Selden's motion to compel is **GRANTED**, and it is

FURTHER ORDERED that the FDA's motion to quash is **DENIED**, and it is

ORDERED that the FDA comply with Selden's subpoenas in accordance with the FDA's *Touhy* regulations, and it is

FURTHER ORDERED that the parties provide this court (and a courtesy copy to the trial court in Massachusetts) with a joint status report outlining the parties' anticipated timing for

the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations.

The parties must file their joint status report within 7 days of this order.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

MEMORANDUM OPINION

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

I. INTRODUCTION

The United States Securities and Exchange Commission ("SEC") filed a securities enforcement action against Richard F. Selden in federal court in Massachusetts. In preparing his defense, Selden served two subpoenas on the United States Food and Drug Administration and the Center for Biologics Evaluation and Review, a division of the Food and Drug Administration (collectively, the "FDA").

In the instant action, Selden seeks to compel the subpoenas *duces tecum* he served on the FDA. The FDA seeks to quash the subpoenas arguing that Selden failed to comply with the FDA's regulations governing requests for document production and that the subpoenas are

unduly burdensome. Because the FDA's regulations require it to treat subpoenas as requests for records, and because the FDA has not yet processed Selden's subpoenas in accordance with those regulations, the court compels the FDA's compliance with the subpoenas and denies the FDA's motion to quash. Because the FDA has not yet processed Selden's subpoenas, the court cannot assess whether any document production would be unduly burdensome.

II. BACKGROUND

A. Factual Background

On September 1, 2005, the SEC filed a securities enforcement action against Richard F. Selden in the United States District Court for the District of Massachusetts. *SEC v. Selden*, Civ. No. 05-11805 (D. Mass. Sept. 1, 2005); Mot. to Compel at 1. The SEC's complaint alleges that Selden, in his position as chief operating officer for Transkaryotic Therapies, Inc. ("TKT"), a small biotechnologies firm, interfered with the FDA's review of TKT's drug, Replagal, for domestic marketing approval.[1] Mot. to Compel at 1. Specifically, the SEC alleges that Selden made "materially misleading public statements by TKT about the status of the FDA application for Replagal." Mot. to Compel, Ex. C ¶ 1.

To prepare his defense, Selden served two subpoenas on the FDA for testimony and

[1] Replagal is a TKT drug used for the treatment of Fabry disease, a rare genetic disorder caused by a missing enzyme needed to metabolize lipids in the body. Mot. to Compel at 1.

documents relating to Replagal, TKT, and Selden, or otherwise relating to the underlying case.[2] Mot. to Compel at 2; Mot. to Compel Ex. A-B; Mot. to Quash at 2-3. In a letter dated November 9, 2005, the FDA objected to the subpoenas and requested that Selden withdraw them.[3] Mot. to Compel Ex. D ("Objection Letter"). In numerous letter between the FDA and Selden, the FDA reiterated its objections to the subpoenas and encouraged Selden to file his request for documents pursuant to the Freedom of Information Act ("FOIA"). Mot. to Quash at 5-6. Selden did not withdraw the subpoenas but instead reasserted his need for the information in preparing his defense in the securities enforcement action in Massachusetts. Mot. to Compel at 2.

2. Procedural Background

On February 10, 2006, this court held the case in abeyance pending a ruling by the United States Court of Appeals for the District of Columbia in the case of *Yousuf v. Samantar*, 451 F.3d 248 (D.C. Cir. 2006). Order (Feb. 10, 2006). On June 16, 2006, the Court of Appeals issued its ruling and held that a government agency is a "person" under Rule 45 and, therefore, can be the target of a third-party subpoena. *Yousuf*, 451 F.3d 248. Following the Court of

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[2] The subpoenas for testimony are not at issue here. The FDA responded to Selden's request for testimony by allowing the deposition of Dr. Marc K. Walton and denying Selden's request for testimony from James Kaiser, Rafel Rieves, and Karen Weiss. Supplemental Mem. in Supp. of Mot. to Quash Ex. 2. Selden has not objected to the FDA's denial of his request for testimony.

[3] The FDA objects to the subpoenas on the grounds that (1) the FDA is not a "person" within the meaning of Rule 45 and therefore cannot be the subject of a third-party subpoena; (2) the subpoenas do not comply with the FDA's *Touhy* regulations; (3) the requested documents contain "trade secrets and confidential commercial information;" (4) the requested documents are "exempt from public disclosure by the deliberative process privilege and personal privacy regulations;" (5) the subpoenas do not give the FDA "a reasonable time to respond;" and (6) the subpoenas are "unduly burdensome and over broad because they [seek] documents that [are] more than 18 years old, and because they [seek] certain documents that are publicly available in electronic format on the internet." Mot. to Quash at 4-5; Mot. to Compel Ex. D ("Objection Letter").

Appeals' decision, the parties submitted supplemental memoranda to the court addressing the applicability of *Yousuf* to the present case. Supplemental Mem. in Supp. of Mot. to Compel ("Supp. Mem. to Compel"); Supp. Mem. in Support of Mot. to Quash ("Supp. Mem. to Quash").

In his supplemental memorandum, Selden again seeks the FDA's compliance with the subpoenas and asks the court to compel full disclosure by August 31, 2006, so that Selden can prepare his defense in the Massachusetts action.[4] *Id.* The FDA continues to object to the subpoenas on the grounds that (1) the subpoenas do not comply with the FDA's *Touhy* regulations governing information requests, and that (2) the FDA would be unduly burdened by compliance with the subpoenas.[5] Supp. Mem. to Quash, 6-11. The FDA, therefore, asks the court to quash the subpoenas or, in the alternative, to (1) narrow the scope of the subpoenas; (2) provide a "reasonable time period" for the FDA to respond; and/or (3) require Selden pay the costs of the requested production. *Id.* at 12-14. The court now turns to these claims.

III. ANALYSIS

1. Legal Standard for *Touhy* Regulations

A federal government agency may create procedures for responding to subpoenas and requests for testimony pursuant to 5 U.S.C. § 301, the federal "housekeeping" statute. *Bobreski v. EPA*, 284 F. Supp. 2d 67, 73 (D.D.C. 2003); *see also United States ex rel. Touhy v. Ragen*, 340

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[4] According to Selden, the parties in the Massachusetts action must complete all written discovery by October 30, 2006. Supp. Mem. to Compel, 8.

[5] Following the Court of Appeals' decision in *Yousuf*, the FDA has abandoned its claim that the government is not a "person" within the meaning of Rule 45. *See* Supp. Mot. to Quash, 1-2.

U.S. 462, 468 (1951). Specifically, § 301 authorizes the head of an agency to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use and preservation of its records, papers and property." *Bobreski*, 284 F. Supp. 2d at 73 (quoting 5 U.S.C. § 301). These regulations, generally called *Touhy* regulations, serve the government's need to make a "centraliz[ed] determination as to whether subpoenas duces tecum will be willingly obeyed or challenged[.]" *Touhy*, 340 U.S. at 468.

B. The Court Grants Selden's Motion to Compel and Denies the FDA's Motion to Quash the Subpoenas

The FDA maintains that Selden's subpoenas did not constitute valid requests for documents under the FDA's *Touhy* regulations. Mot. to Quash at 17-21; Supp. Mot. to Quash at 6-9. The FDA claims, therefore, that it is not required to respond to the subpoenas. *Id.*

Federal agencies must "follow their own rules, even gratuitous procedural rules that limit otherwise discretionary actions." *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003) (citing *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)). Under the FDA's own rules, "[a]ny request for records of the Food and Drug Administration, whether it be by letter *or by a subpoena duces tecum* or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part[.]" 21 C.F.R. § 20.2(a) (emphasis added). Under Subpart B, the FDA handles subpoenas *duces tecum* in accordance with the procedures for the production of all agency records pursuant to FOIA. 21 C.F.R. § 20.2(b).

Holding the FDA to its own rules then, the FDA must treat the subpoenas as requests for documents pursuant to its *Touhy* regulations and respond in kind. *Id.*; *see also* Supp. Mem. to

Quash Ex. 3 (Apr. 6, 2006 Selden Letter) (identifying the FDA's own regulations as requiring subpoenas to be treated as *Touhy* requests). And because the FDA must treat the subpoenas *duces tecum* as requests for documents under its *Touhy* regulations, the FDA must respond to Selden's subpoenas pursuant to its *Touhy* regulations.[6] Accordingly, the court grants Selden's motion to compel and denies the FDA's motion to quash the subpoenas.

C. The Court Declines to Rule on Whether the Subpoenas are Unduly Burdensome

The FDA must submit the subpoenas to its *Touhy* process pursuant to the court's ruling. The FDA argues, however, that compliance with the subpoenas would be unduly burdensome. But, because the agency has not yet taken the appropriate administrative action on these requests under its regulations, the extent of any document production pursuant to Selden's request is, at this juncture, speculative. The court, therefore, is unable to assess the FDA's argument that compliance would be burdensome. Accordingly, the court declines to rule on the FDA's objection that the subpoenas are unduly burdensome, declines to rule on the FDA's motion to modify the subpoenas, and orders the FDA to proceed under the policies it has set forth in its

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[6] Relying on the Court of Appeals' decision in *Yousuf*, Selden contends that he is entitled to immediate access to the documents; that he need not wait on the FDA's *Touhy* process. Supp. Mem. to Compel at 6-7. In *Yousuf*, the D.C. Circuit held that a government agency could be the subject of a third-party subpoena under Rule 45 of the Federal Rules of Civil Procedure. 451 F.3d at 250. Selden reads this decision as allowing a litigant, in subpoenaing a government agency, to bypass that agency's *Touhy* process altogether. Supp. Mem. to Compel at 6-7. Selden misapprehends the Court of Appeals' decision. In *Yousuf*, the court did not suggest that a litigant would be able to bypass a federal agency's *Touhy* regulations by subpoenaing the agency. In fact, the court explicitly acknowledged the role of *Touhy* regulations as the vehicle through which a federal agency responds to a subpoena *duces tecum*. *Yousuf*, 451 F.3d at 257 (citing *Touhy*, 340 U.S. at 464, 469). Accordingly, Selden must wait for the FDA to process his subpoenas under its *Touhy* regulations.

Touhy regulations.[7]

IV. CONCLUSION

For the foregoing reasons the court, this 16th day of August, 2006, compels the FDA's compliance with Selden's subpoenas in accordance with the FDA's *Touhy* regulations. An order instructing the parties in a manner consistent with this Memorandum Opinion is issued contemporaneously.

RICARDO M. URBINA
United States District Judge

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[7] The court notes that the FDA must proceed through its *Touhy* process prior to any document production and that, under its procedures, it will treat the subpoenas as FOIA requests. 21 C.F.R. § 20. The FDA indicates that the parties have made "significant progress" in negotiating the scope of Selden's document requests and that Selden has already received approximately 300 pages of responsive documents from the FDA. Supp. Mem. to Quash at 4-5. Selden contends that, although engaging in dialogue, the FDA has not produced any documents in response to his subpoenas. Supp. Mem. to Compel, 8.

Though delay will not affect this court's docket, the court reminds the FDA that Selden wants these documents to prepare a defense to the pending action in the United States District Court for the District of Massachusetts. Thus, the FDA must engage Selden's request, and formulate a response, with dispatch (rather than place Selden's subpoena request at the back of the FOIA que). Toward that end, the court orders the parties to provide this court and the trial court in Massachusetts with a joint status report outlining the parties' anticipated timing for the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The court anticipates and expects the FDA's good faith, prompt, and satisfactory compliance in this endeavor.

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	

DEFENDANT RICHARD F. SELDEN'S STATEMENT IN CONNECTION WITH THE SEPTEMBER 28, 2006 STATUS CONFERENCE

In connection with the status conference scheduled before this Court on Thursday, September 28, 2006, defendant Richard F. Selden respectfully submits the following statement regarding the U.S. Food and Drug Administration's ("FDA's") recent statement that it will take the agency 22 months to comply with Dr. Selden's federal subpoenas issued on October 28, 2005 (the "Subpoenas").

Preliminary Statement

On August 16, 2006, U.S. District Judge Ricardo M. Urbina issued an order in S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C.), granting in its entirety Dr. Selden's motion to compel the FDA's compliance with the Subpoenas (the "D.C. Order").[1] However, notwithstanding the pretrial schedule in this action (which, among other things, provides that all written discovery must be completed by October 30, 2006), the FDA has said it will need another 22 months to comply with the Subpoenas.

[1] Dr. Selden submitted a copy of the D.C. Order and related Memorandum Opinion to this Court with his Notice Of Filing Joint Status Report (Docket No. 16, filed Aug. 25, 2006).

Background

This is a securities enforcement action brought against Dr. Richard F. Selden by the U.S. Securities and Exchange Commission ("SEC"). Dr. Selden is the founder and former President and Chief Executive Officer of Transkaryotic Therapies, Inc. ("TKT"), a small biotechnology firm previously located in Cambridge, Massachusetts.[2] The SEC alleges that Dr. Selden violated the federal securities laws in connection with the FDA's review for domestic marketing approval of Replagal, TKT's drug for the treatment of Fabry disease, a rare genetic disorder. According to the Complaint, Dr. Selden, in his position as CEO of TKT, is responsible for a "series of [allegedly] materially misleading public statements by TKT about the status of the FDA application for Replagal." Complaint, SEC v. Selden (filed Sept. 1, 2005) ("Compl."), ¶ 1.

The SEC's entire case is based on the FDA's review of TKT's application for Replagal, its communications with TKT in this regard, and the steps both the FDA and TKT perceived as necessary for Replagal to obtain marketing approval in the United States. See, e.g., Compl. ¶¶ 2-4, 12-14, 21-22, 24-26, 28-33, 35, 38-39, 41-42, 44-53, 55, 59-60, 62, 66, 70 & 74.

Given the critical importance of FDA evidence to Dr. Selden's defense, on October 28, 2005 -- the first day he was permitted to do so by the Federal Rules of Civil Procedure -- Dr. Selden issued two federal subpoenas on the FDA going directly to the issues raised by the SEC's Complaint. The FDA opposed the Subpoenas. That began an eleven-month effort by Dr. Selden to secure his needed FDA discovery. The brief chronology of that effort is as follows:

---

[2] In July 2005, TKT was acquired by Shire Pharmaceuticals Group plc, a U.K. corporation.

Chronology

October 2005

- Dr. Selden issued the Subpoenas out of U.S. District Court for the District of Columbia ("D.C. Court"). The FDA first refused to accept service of the Subpoenas, then did so several days later.

November 2005

- The FDA Chief Counsel's Office informed Dr. Selden by letter that it would not comply in any respect with the Subpoenas and requested that they be withdrawn.

- Dr. Selden responded to the FDA's letter, restating the essential nature of the subpoenaed discovery, reviewing the FDA's extensive prior cooperation with the SEC in this case, reviewing the relevant case law, and requesting that the FDA reconsider its position.

- This Court held the Rule 16 scheduling conference. At the conference, counsel for Dr. Selden informed the Court of the Subpoenas and the discovery dispute with the FDA, and advised that the open issue of FDA discovery could impact the scheduling of this action going forward.

- When agreement with the FDA could not be reached, Dr. Selden filed a motion to compel in the D.C. Court. S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C., filed Nov. 23, 2005).

December 2005

- The FDA filed its opposition to Dr. Selden's motion to compel and cross-moved to quash the Subpoenas. Among the FDA's asserted grounds was the position that the FDA is not a "person" under Fed. R. Civ. P. 45 and thus cannot be subpoenaed.

- Dr. Selden filed his opposition to the FDA's motion to quash and reply in further support of his motion to compel.

January 2006

- The FDA filed its reply in further support of its motion to quash.

February 2006

- The D.C. Court issued an order holding the matter in abeyance pending decision by the U.S. Court of Appeals for the District of Columbia Circuit in Yousuf v. Samantar, No. 05-5197 (D.C. Cir.) ("Yousuf"), on the grounds that the enforcement of the federal governmental subpoena

in that case raised some of the same issues raised during the proceedings before the D.C. Court.[3]

- Days later, Dr. Selden moved the U.S. Court of Appeals for leave to file a brief in Yousuf as an amici curia.

- The Department of Justice filed a brief opposing Dr. Selden's motion for leave, and the U.S. Court of Appeals denied Dr. Selden's motion.

- Dr. Selden filed an unopposed motion with this Court seeking to extend all pretrial deadlines by six months in light of the FDA's refusal to comply with the Subpoenas as well as the continuing proceedings in the D.C. Court. (See Docket Nos. 14 & 15.)

March 2006

- This Court granted Dr. Selden's motion to amend the Scheduling Order and set the following revised deadlines, among others:

Sept. 29, 2006:	Last day to serve written discovery
Oct. 30, 2006:	Last day to answer written discovery
Feb. 28, 2007:	Last day for fact depositions
June 30, 2007:	Last day of expert discovery
Aug. 17, 2007:	Last day to file dispositive motions

- In this matter, counsel for the SEC contacted Dr. Selden and offered to assist Dr. Selden in obtaining discovery from the FDA.

- Dr. Selden served "Touhy" requests for testimony on the FDA.[4]

April-May 2006

- At the prompting of the SEC, the FDA began a dialogue with Dr. Selden. Numerous phone calls took place. During this time Dr. Selden agreed to narrow several of his requests.

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[3] A copy of the D.C. Court's February 2006 Order was provided to this Court in connection with Dr. Selden's unopposed motion to extend the Scheduling Order in this matter. (See Docket No. 15, Ex. 1.)

[4] The FDA's Touhy regulations (named after United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951)), are contained at 21 C.F.R. Part 20, and provide a mechanism for private citizens (whether or not in litigation) to request testimony and documents from the FDA. With respect to documents, Dr. Selden complied with Touhy by serving the subpoenas. Dr. Selden decided to make Touhy requests for testimony in light of the FDA's continued intransigence and the prospect of several more months of delay in obtaining relief in court.

June 2006

- The D.C. Circuit issued its ruling in Yousuf, holding, among other things, that federal governmental agencies (such as the FDA) are "persons" subject to subpoena under Rule 45. Yousuf v. Samantar, 451 F.3d 248, 252-57 (D.C. Cir. 2006).

- Pursuant to the D.C. Court's February 2006 Order, Dr. Selden and the FDA submitted memoranda regarding the impact of the Yousuf decision on their respective motions to compel and to quash the Subpoenas.

July 2006

- More than two months after receiving Dr. Selden's March 2006 Touhy requests, the FDA responded by refusing to produce any of the witnesses requested by Dr. Selden for testimony, but for the witness from whom the SEC had previously taken testimony. The FDA's sole stated rationale for denying the testimony was that the testimony would be "duplicative."

- Dr. Selden responded to the FDA's Touhy letter, pointing out the many respects in which the testimony being sought is not duplicative and requesting that the FDA reconsider its refusal to produce the witnesses for testimony. The FDA has never responded to this letter.

- With respect to documents, the SEC-initiated dialogue between Dr. Selden and the FDA continued; however, despite making progress on the substance, the FDA had yet to produce a single piece of paper.

August 2006

- Judge Urbina granted in its entirety Dr. Selden's motion to compel FDA compliance with the Subpoenas and denied the FDA's motion to quash same. The Court also required the parties to submit a Joint Status Report within fifteen days and to provide a courtesy copy to this Court.

- The Joint Status Report was filed with the D.C. Court and a courtesy copy was provided to this Court. (See Docket No. 16.) Among other things, the FDA stated in the Report that it will take the agency 22 months to review and produce the requested documents. (According to the FDA's estimate, one person working full time will need six-to-seven weeks to review and produce a single box of documents.)

- Given the FDA's 22-month predicted production, and other issues identified in the Joint Status Report, Dr. Selden requested a conference before the D.C. Court. No such conference has yet been scheduled.

As the above clearly demonstrates, Dr. Selden promptly, diligently and aggressively pursued discovery from the FDA in this matter -- by far the most important non-party to his defense -- for nearly eleven months. Still, notwithstanding the D.C. District Court's favorable ruling, Dr. Selden has not come close to obtaining the FDA discovery he has sought since October of 2005.

Conclusion

Consequently, while Dr. Selden continues to pursue substantive relief before the D.C. Court in response to the FDA's positions, he respectfully seeks this Court's guidance on the pretrial schedule so he may mount a fair and complete defense to the SEC's charges.

Dated: September 20, 2006
Boston, Massachusetts

Respectfully submitted,

/s/ Thomas J. Dougherty
Thomas J. Dougherty (BBO #132300)
Justin J. Daniels (BBO #656118)
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
One Beacon Street
Boston, Massachusetts 02108
(617) 573-4800
dougherty@skadden.com
jdaniels@skadden.com

CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on September 20, 2006.

Dated: September 20, 2006

/s/ Justin J. Daniels
Justin J. Daniels

EXHIBIT 4

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No.
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	Related To: S.E.C. v. Richard F. Selden, Civil Action No. 05-11805-NMG
Defendants.	:	

AFFIDAVIT OF JUSTIN J. DANIELS IN SUPPORT OF PLAINTIFF'S MOTION FOR ORDER TO SHOW CAUSE AND PRELIMINARY INJUNCTION

COMMONWEALTH OF MASSACHUSETTS)
) ss.:
SUFFOLK COUNTY)

I, JUSTIN J. DANIELS, being duly sworn, depose and say:

1. I am a member of the bar of the Commonwealth of Massachusetts and a counsel with the law firm of Skadden, Arps, Slate, Meagher & Flom LLP, representing Plaintiff Richard F. Selden ("Dr. Selden") in the above-captioned action.

2. I make this Affidavit in connection with Plaintiff's Motion For Order To Show Cause And Preliminary Injunction, based on my personal knowledge and review of the available documents.

3. On October 22, 2002, approximately three weeks after the SEC commenced its investigation, the SEC sent a request for materials to the FDA in the form of

an access letter. See Ex. A.

4. Within four weeks, on November 18, 2002, the FDA provided the first of several subsequent productions of documents to the SEC.

5. On January 23, 2003, the FDA produced additional documents to the SEC.

6. On February 10, 2003, the SEC sent a second request for documents from the FDA. See Ex. B.

7. On May 15, 2003, the SEC sent copies of press releases to the FDA relating to the SEC's investigation of TKT. See Ex. C.

8. On May 28, 2003, the FDA produced additional documents to the SEC. See Ex. D.

9. On May 30, 2003, with the knowledge of the FDA General Counsel's Office, the SEC conducted an informal, "off the record" interview of Dr. Mark Walton, one of the key FDA reviewers of TKT's biologics license application for Replagal. See Ex. E.

10. On June 25, 2003, the SEC sought the formal testimony from Dr. Walton pursuant to 21 C.F.R. § 20.1, et seq. See Ex. F.

11. On June 26, 2003, the FDA responded to the SEC's request for Dr. Walton's testimony. The FDA authorized the testimony "[i]n keeping with our policy of assisting other government agencies in matters related to the protection of the public health." See Ex. F.

12. On July 22, 2003, Dr. Walton gave sworn testimony to the SEC.

13. On September 1, 2005, the SEC filed a Complaint against Dr. Selden in the United States District Court for the District of Massachusetts ("SEC Action"). See Ex. G.

14. On October 28, 2005, in connection with the SEC Action, Dr. Selden issued two federal subpoenas out of the United States District Court for the District of Columbia ("D.C. Court"). The FDA first refused to accept service of the Subpoenas, then did so several days later. See Exs. H & I.

15. On November 9, 2005, the FDA Chief Counsel's Office informed Dr. Selden by letter that it would not comply in any respect with the Subpoenas and requested that they be withdrawn. See Ex. J.

16. On November 15, 2005, Dr. Selden responded to the FDA's letter, restating the essential nature of the subpoenaed discovery, reviewing the FDA's extensive prior cooperation with the SEC in this case, reviewing the relevant case law, and requesting that the FDA reconsider its position. See Ex. K.

17. On November 17, 2005, the Court in the SEC Action held a Rule 16 scheduling conference. At that conference, counsel for Dr. Selden informed the Court of the Subpoenas and the discovery dispute with the FDA, and advised that the open issue of FDA discovery could impact the scheduling of the SEC Action going forward.

18. When agreement with the FDA could not be reached, Dr. Selden filed a motion to compel in the D.C. Court. S.E.C. v. Selden, No. 1:05-mc-00476-RMU (D.D.C., filed Nov. 23, 2005).

19. On February 10, 2006, the D.C. Court issued an order holding the matter in abeyance pending decision by the U.S. Court of Appeals for the District of

Columbia Circuit in Yousuf v. Samantar, No. 05-5197 (D.C. Cir.) ("Yousuf"), on the grounds that the enforcement of the federal governmental subpoena in that case raised some of the same issues raised during the proceedings before the D.C. Court. See Ex. L.

20. Days later, Dr. Selden moved the U.S. Court of Appeals for leave to file a brief in Yousuf as an amici curia.

21. The Department of Justice filed a brief opposing Dr. Selden's motion for leave, and the U.S. Court of Appeals denied Dr. Selden's motion.

22. Dr. Selden filed an unopposed motion with this Court seeking to extend all pretrial deadlines by six months in light of the FDA's refusal to comply with the Subpoenas as well as the continuing proceedings in the D.C. Court. See S.E.C. v. Selden, Docket Nos. 14 & 15.

23. On March 24, 2006, this Court granted Dr. Selden's motion to amend the Scheduling Order and set the following revised deadlines, among others:

Sept. 29, 2006:	Last day to serve written discovery
Oct. 30, 2006:	Last day to answer written discovery
Feb. 28, 2007:	Last day for fact depositions
June 30, 2007:	Last day of expert discovery
Aug. 17, 2007:	Last day to file dispositive motions

24. On March 29, 2006, Dr. Selden served "Touhy" requests for testimony on the FDA. See Ex. M.

25. During April and May 2006, at the prompting of the SEC, the FDA began a dialogue with Dr. Selden. Numerous phone calls took place. During this time Dr. Selden agreed to narrow several of his requests.

26. On June 16, 2006, the D.C. Circuit issued its ruling in Yousuf v. Samantar, 451 F.3d 248 (D.C. Cir. 2006).

27. On June 30, 2006, pursuant to the D.C. Court's February 10, 2006 Order, Dr. Selden and the FDA submitted memoranda regarding the impact of the Yousuf decision on their respective motions before the D.C. Court.

28. On July 10, 2006, more than three months after the FDA received Dr. Selden's March 2006 Touhy requests, Dr. Selden received a response from the FDA. The FDA stated it was refusing to produce any of the witnesses requested by Dr. Selden for testimony, but for the witness from whom the SEC had previously taken testimony, Dr. Mark Walton. The FDA's sole stated rationale for denying the testimony was that the testimony would be "likely be duplicative." See Ex. N.

29. On July 12, 2006, Dr. Selden responded to the FDA's Touhy letter, pointing out the many respects in which the testimony being sought is not duplicative and requesting the FDA to reconsider its refusal to produce the witnesses. See Ex. O. Although I was informed on at least two occasions by FDA counsel that a response to letter from FDA would be forthcoming, to date there has been no response from the FDA.

30. During July 2006, with respect to documents, the SEC-initiated dialogue between Dr. Selden and the FDA continued; however, despite making progress on the substance, the FDA had yet to produce a single piece of paper.

31. On August 16, 2006, the D.C. Court granted in its entirety Dr. Selden's motion to compel FDA compliance with the Subpoenas and denied the FDA's motion to quash. The Court also directed the parties to submit a Joint Status Report and to provide a courtesy copy to this Court. See Ex. P.

32. On August 25, 2006, a Joint Status Report was filed with the D.C. Court and a courtesy copy was provided to the Court in S.E.C. v. Selden. Among other

things, the FDA stated that it will require twenty-two months to review and produce the agreed-to documents. (According to the FDA's estimate, one person working full time will need six-to-seven weeks to review and produce a single box.) See Ex. Q.

Justin J. Daniels

On this 5th day of October 2006, before me, the undersigned notary public, personally appeared Justin J. Daniels, whom I personally know, who signed the preceding document in my presence, and who swore to me that the contents of the document are truthful and accurate to the best of his knowledge and belief.

(official signature and seal of notary)

My Commission expires: 5/10/13

EXHIBIT A

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
BOSTON DISTRICT OFFICE
6TH FLOOR
73 TREMONT STREET
BOSTON, MASSACHUSETTS 02108

PHONE: (617) 424-5900
FACSIMILE (617) 424-5940

WRITER'S DIRECT DIAL NUMBER
(617) 424-5936

IN REPLYING PLEASE QUOTE

BY FACSIMILE to 301.827.0482 AND FIRST-CLASS MAIL

October 22, 2002

Lana Ogram, Director
Division of Compliance Policy
c/o Anne P. Smith (HFC-230)
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: **Trading in Securities of Transkaryotic Therapies, Inc. (MB-1897)**

Dear Ms. Ogram:

In connection with an investigation into possible violations of the federal securities laws, the Division of Enforcement of the Securities and Exchange Commission requests the following non-public information pursuant to 21 C.F.R. § 20.85:

1. Documents and information reflecting communications and the substance thereof between FDA representatives and officers, employees or representatives of Transkaryotic Therapies, Inc. ("Transkaryotics") relating to the status of approval for Replagal for the time period August 1, 2002 through October 10, 2002;

2. Documents and information reflecting communications and the substance thereof between FDA representatives and officers, employees or representatives of Transkaryotics relating to the possible cancellation of, and the decision to cancel (made on or about September 20, 2002), an FDA advisory committee panel meeting scheduled for September 26-27, 2002 that would have considered Transkaryotics' Replagal application;

3. Documents and information reflecting the Advisory Committee's reasons for canceling the September 26-27 meeting, and the identities and backgrounds of the members of the Advisory Committee; and

4. Identification of and assistance from the FDA representatives that reviewed Transkaryotics' Replagal application and spoke with Transkaryotics' management. These individuals may include, but are not limited to, Duane Reeves, John McCormack, Catherine Ready and Nancy Skladany.

I certify that the information is requested for use in an investigation concerning possible violations of the federal securities laws. I further certify that the activity is authorized by law and the information will only be used for the stated purpose.

With the understanding that the information contained in the FDA's files is confidential, the Commission will not disclose the contents of such files or records without prior written approval by the FDA. Additionally, we will inform the FDA of an attempt to obtain this information by compulsory process. I understand that 21 U.S.C. § 331(j) of the Federal Food, Drug , and Cosmetic Act prohibits disclosure of trade secret information outside the Department of Health and Human Services.

This inquiry by the staff of the Securities and Exchange Commission should not be construed as an indication by the Commission or its staff that any federal securities violations have occurred or are occurring or any reflection upon any person who may have effected any transaction in connection with any such securities.

If you have any questions, or to schedule interviews with the appropriate individuals, please contact John Dugan, Branch Chief, at 617.424.5900 ext. 688, or David Butler, attorney, at 617.424.5900 ext. 613.

Very truly yours,

Kate Poverman
Assistant District Administrator

EXHIBIT B

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
BOSTON DISTRICT OFFICE
6TH FLOOR
73 TREMONT STREET
BOSTON, MASSACHUSETTS 02108
PHONE: (617) 424-5900
FACSIMILE (617) 424-5940

WRITER'S DIRECT DIAL NUMBER
(617) 424-5927

IN REPLYING PLEASE QUOTE

February 10, 2003

BY FACSIMILE to 301.827.0482 AND FIRST-CLASS MAIL

Lana Ogram, Director
Division of Compliance Policy
c/o Anne P. Smith (HFC-230)
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Trading in Securities of Transkaryotic Therapies, Inc. (MB-1897)

Dear Ms. Ogram:

This supplements the staff's access letter of October 22, 2002. In connection with an investigation into possible violations of the federal securities laws, the Division of Enforcement of the Securities and Exchange Commission requests the following non-public information pursuant to 21 C.F.R. § 20.85:

1. Documents and information reflecting communications and the substance thereof between FDA representatives and officers, employees or representatives of Transkaryotic Therapies, Inc. ("Transkaryotics") relating to the application for approval for Replagal for the time period July 1, 2000 through the present;

2. Documents and information reflecting communications and the substance thereof between FDA representatives and officers, employees or representatives of Transkaryotics relating to the possible cancellation or postponement of, and the decision to cancel or postpone (made on or about September 20, 2002), an FDA Advisory Committee ("Committee") panel meeting scheduled for September 26-27, 2002 that would have considered Transkaryotics' Replagal application;

3. Documents and information reflecting the Committee's reasons for canceling or postponing the September 26-27 meeting, and the identities

and backgrounds of the members of the Committee;

4. Documents and information reflecting communications and the substance thereof between FDA representatives and officers, employees or representatives of Transkaryotic relating to the Committee meeting which occurred on January 13-14, 2003 that considered Transkaryotic's Replagal application; and

4. Identification of and assistance from the FDA representatives that reviewed Transkaryotic's Replagal application and spoke with Transkaryotics' management. These individuals may include, but are not limited to, Dr. Mark Walton, Duane Reeves, John McCormack, Catherine Ready and Nancy Skladany.

I certify that the information is requested for use in an investigation concerning possible violations of the federal securities laws. I further certify that the activity is authorized by law and the information will only be used for the stated purpose.

With the understanding that the information contained in the FDA's files is confidential, the Commission will not disclose the contents of such files or records without prior written approval by the FDA. Additionally, we will inform the FDA of an attempt to obtain this information by compulsory process. I understand that 21 U.S.C. § 331(j) of the Federal Food, Drug, and Cosmetic Act prohibits disclosure of trade secret information outside the Department of Health and Human Services.

This inquiry by the staff of the Securities and Exchange Commission should not be construed as an indication by the Commission or its staff that any federal securities violations have occurred or are occurring or any reflection upon any person who may have effected any transaction in connection with any such securities.

If you have any questions, or to schedule interviews with the appropriate individuals, please contact John Dugan, Branch Chief, at 617.424.5900 ext. 688, or David Butler, attorney, at 617.424.5900 ext. 613.

Very truly yours,

David P. Bergers
Assistant District Administrator

EXHIBIT C

TELECOPIER TRANSMITTAL COVER SHEET

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

BOSTON DISTRICT OFFICE
73 TREMONT STREET
BOSTON, MA 02108
TELEFAX NO. 617.424.5940

TO: Ms. Marianne Brill
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

FAX NUMBER: 301.827.6748

FROM: David E. Butler
617.424.5900 ext. 613

*TOTAL NUMBER OF PAGES (INCLUDING COVER PAGE): 5

Date: May 15, 2003

Time: 10:22am

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Transkaryotic probed over FDA dealings

By Naomi Aoki 5/15
GLOBE STAFF

Transkaryotic Therapies Inc. disclosed yesterday that the Securities and Exchange Commission has opened an investigation into the company's dealings with the Food and Drug Administration as it raced with cross-town rival Genzyme Corp. to bring a treatment for a rare genetic disorder known as Fabry disease to the US market.

The SEC notified company officials yesterday that a formal investigation is underway, and they said they plan to cooperate fully with investigators. The regulatory agency also is looking into transactions in the company's stock.

In October, former TKT chief executive Richard Selden told investors that the FDA had deemed a key portion of its data from clinical studies supporting TKT's drug, Replagal, to be "uninterpretable." Selden, however, described the company's application for approval as "compelling" and assured investors he was confident the drug would be approved. Despite Selden's comments, the stock fell $20.50, or 62 percent, on the news.

At an unusual public meeting the FDA called in January to examine both Genzyme's and TKT's Fabry drug applications, an agency reviewer said the FDA had informed the company by letter on Dec. 22, 2000 — almost two years prior to the October announcement — that its data did not support approval of Replagal and recommended additional study. At the time, all that TKT disclosed to investors was that the FDA "has asked for further explanation and requested additional data."

Since January, TKT has been hit with a slew of shareholder lawsuits from investors who believe the company withheld

TKT, Page E2

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SEC probes TKT over dealings with FDA

▶ TKT
Continued from Page E1

information from the public.

"The case is going to be won or lost on what the FDA minutes and correspondence with the company reflect, and on key witness testimony about what the company knew and when they knew it," said Jennifer Chao, an analyst with RBC Capital Markets in New York.

Both TKT and Genzyme invested hundreds of millions of dollars in the winner-take-all battle to bring a Fabry drug to market. FDA rules require that only one drug be approved to treat a rare disease such as Fabry, which affects only a few thousand people worldwide. The "orphan drug" act gives a company seven years to sell its drug unhindered by competition in exchange for being the first to develop a drug to treat a rare disease.

Last month, the FDA approved Genzyme's drug, Fabrazyme, effectively blocking Replagal from the US market.

"We're not altogether surprised that the SEC would take this action," Chao said. "It's impossible to speculate what the outcome could be because so many important facts have not been publicly disclosed."

Selden resigned from the company in February, ending a 15-year tenure at the firm he founded. Michael Astrue, who had been the company's senior vice president and general counsel, was appointed president and chief executive.

"There are questions about the old management for sure," said Bill Tanner, an analyst with Leerink Swann & Co. in Boston. "Even with new management, there's going to be a residual bad taste in investors' mouths about TKT, and this will do nothing to attenuate that."

Shares in TKT closed up 1 cent to $7.09 yesterday in trading on the Nasdaq Stock Market before news of the investigation was released.

Naomi Aoki can be reached at naoki@globe.com.

Globe 5/15

Transkaryotic acknowledges probe by SEC

By JENNIFER HELDT POWELL

Transkaryotic Therapies Inc. said yesterday that the Securities and Exchange Commission has ordered an investigation of its disclosures and public filings regarding Replagal, its experimental treatment for Fabry disease.

The investigation includes information submitted to the SEC regarding the status of the U.S. Food and Drug Administration's approval process for the drug.

The agency is also investigating transactions of company securities.

Officials of the Cambridge biotech said they are cooperating with the investigation, which comes on the heels of a class-action lawsuit filed following a steep stock drop last year. On Oct. 2, company shares slipped to $15.52 from about $33.25 when it announced FDA concerns about Replagal.

Regulators said clinical data from major studies wouldn't support the product's approval.

A competing product by Genzyme Corp., also of Cambridge, has since been approved. Genzyme won seven years of market exclusivity for the product under an FDA program to promote the development of drugs for rare diseases.

A lawsuit charges misrepresention of evidence showing Replagal would work against Fabry disease.

Fabry disease, a metabolic disorder, affects 5,000 to 10,000 people.

Replagal is available in Europe.

Transkaryotic shares have dropped 28 percent this year. They ended yesterday at $1.09.

A lawsuit filed by Berger & Montague P.C., based in Philadelphia, alleges that Transkaryotic misled investors by filing "false and misleading statements" between Jan. 3, 2001, and Jan. 14, 2003.

The suit charges that the company misrepresented the adequacy of the evidence showing Replagal would work against Fabry disease.

In April, the company said a shareholder derivative lawsuit was filed in Superior Court against its board. The claims were similar to the class-action lawsuit.

Company officials have said they would defend the company vigorously against the claims.

Herald 5/15

THE NEW YORK TIMES, THURSDAY, MAY 15, 2003

S.E.C. Investigates Transkaryotic Over Drug Approval

By ANDREW POLLACK

CAMBRIDGE, Mass., May 14 — The Securities and Exchange Commission is investigating whether Transkaryotic Therapies misled investors about the regulatory status of a drug it was developing, the company said today.

The investigation of Transkaryotic, a biotechnology company based here, recalls the case involving ImClone Systems and its cancer drug, which soured investors on the biotechnology industry.

Transkaryotic said it had received a formal order of investigation from the S.E.C. concerning public statements about the status of the Food and Drug Administration approval process for its drug for Fabry disease, a rare inherited disorder. It said the investigation also concerned stock transactions.

Transkaryotic, which is known as TKT, said it would cooperate with the investigation. The S.E.C. does not comment on investigations it is undertaking.

The company, meanwhile, faces several shareholder lawsuits asserting that it misled investors.

TKT's stock dropped 62 percent on a single day in October when it announced that the F.D.A. staff did not agree with the main data supporting its Fabry drug, Replagal. Some angry analysts and investors said that TKT had been assuring them until then that the drug was on track for approval.

On that day in October, TKT management said that the company still expected approval based on other data. But according to some of the shareholder lawsuits, it was revealed at an F.D.A. advisory panel meeting in January that the agency also had reservations about that data and had informed TKT of its reservations as early as December 2000.

The panel did not recommend approval of Replagal and it has not been approved. Instead, the F.D.A. in April approved a rival drug from the Genzyme Corporation. That will probably keep TKT's drug from the market for seven years, under the terms of a federal law concerning drugs for rare diseases.

TKT has denied accusations in the shareholder lawsuits. It also said it did not know about the F.D.A.'s concerns until just before it made it its announcement in October.

The TKT case bears some resemblance to that of ImClone, which had assured investors that its cancer drug Erbitux would easily win approval. But the F.D.A. rejected ImClone's application. It later became clear that the agency had had concerns about the design of ImClone's clinical trial for more than a year.

Questions arise about the regulatory status of a treatment for a rare disorder.

Both cases highlight a dilemma for biotechnology investors. The F.D.A. usually does not publicly discuss drugs that are under consideration for approval. That leaves investors almost totally dependent on the company's version of what is happening.

Samuel D. Waksal, ImClone's founder and chief executive at the time of the F.D.A. rejection, was later indicted for tipping off relatives to sell shares of ImClone in the days before the F.D.A. decision was announced. He has pleaded guilty to several charges.

It is not clear what stock transactions the S.E.C. is looking at in the case of TKT. One of the shareholder lawsuits, filed by Scott & Scott, says that TKT raised $267 million in stock offerings since January 2001, and that Richard F. Selden, the company's founder and former chief executive, sold $2.8 million in stock during that period.

Dr. Selden resigned in February and since then other top managers, including the chief financial officer, have also left. The new chief executive, Michael J. Astrue, had been the company's general counsel.

EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

MAY 28 2003

David Butler, Esq.
U.S. Securities and Exchange Commission
73 Tremont Street, Third Floor
Boston, Massachusetts 02109

Re: Trading in the Securities of Transkaryotic Therapies, Inc. (MB-1897)

Dear Mr. Butler:

The information you requested from the Food and Drug Administration records regarding Transkaryotic Therapies, Inc is attached.

Please note that the information provided is not publicly disclosable without written permission from the Food and Drug Administration.

If I can be of further assistance, or answer any additional questions, you may contact Marieann R. Brill, Consumer Safety Officer or me at (301) 827-6220.

Sincerely,

Jerome C. Davis

Jerome C. Davis
Chief, Program Surveillance Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

EXHIBIT E

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
BOSTON DISTRICT OFFICE
6TH FLOOR
73 TREMONT STREET
BOSTON, MASSACHUSETTS 02108
PHONE: (617) 424-5900
FACSIMILE (617) 424-5940

WRITER'S DIRECT DIAL NUMBER
(617) 424-5900, EXT. 613

IN REPLYING PLEASE QUOTE

June 5, 2003

Peter C. Beckerman
Associate General Counsel
Food & Drug Administration
5600 Fishers Lane
GCF-1
Rockville, MD 20857

Re: In the Matter of: Transkaryotic Therapies, Inc. (B-1897)

Dear Mr. Beckerman:

Please convey my thanks to Dr. Walton for meeting with the staff on May 30. I enclose a statement of routine uses which describes the uses made of information provided to the staff, and which the staff routinely provides to persons providing information. If we need additional information I will contact you.

Very truly yours,

David B. Butler
Senior Enforcement Counsel

Attachment: SEC 1662

EXHIBIT F

DEPARTMENT OF HEALTH AND HUMAN SERVICE Public Health Service

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

June 26, 2003

Mr. David P. Bergers
Assistant District Administrator
U. S. Securities and Exchange Commission
Boston District Office
73 Tremont Street
Boston, MA 02108

Dear Mr. Bergers:

This is in response to your June 25, 2003 letter to the Food and Drug Administration. Your letter requested authorization for the testimony of Dr. Marc K. Walton regarding the firm Transkaryotic Therapies, Inc.

As Director of the Division of Compliance Policy, I have been delegated the authority by the Commissioner to review any requests made under 21 C.F.R. § 20.1. See 21 C.F.R. § 5.23(a)(2). In keeping with our policy of assisting other government agencies in matters related to the protection of the public health, pursuant to 21 CFR § 20.1, I am authorizing the testimony of Dr. Marc K. Walton . You may contact Dr. Walton directly at 301-827-5096 regarding the specific arrangements related to his testimony.

If you have any other questions, please contact Peter Beckerman in the Office of General Counsel at (301) 827-1699.

Sincerely yours,

Sharon M. Sheehan
for

Lana L. Ogram
Director
Division of Compliance Policy

cc: David E. Butler, Esq.
U. S. Securities and Exchange Commission

EXHIBIT G

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

RICHARD B. SELDEN,

Defendant.

Civil Action No. 05 11805 NMG

COMPLAINT

Plaintiff Securities and Exchange Commission ("Commission") alleges the following against defendant Richard B. Selden ("Selden"):

SUMMARY

1. This case arises from material misrepresentations by Transkaryotic Therapies, Inc. ("TKT"), a bio-pharmaceutical company based in Cambridge, Massachusetts, and by defendant Selden, TKT's former CEO. Between at least October 2000 and October 2002, TKT and Selden misrepresented that clinical trials for TKT's flagship drug, Replagal, were a success and made positive statements about Replagal's chances of being approved for sale in the U.S. by the U.S. Food and Drug Administration ("FDA"). In fact, beginning in January 2001, the FDA had informed TKT that its principal clinical trial was a failure and that Replagal would not receive FDA approval based on that trial. At all relevant times, defendant Selden was the CEO of TKT and knew the negative information about Replagal. Nevertheless, he made, signed, participated in, or otherwise authorized a series of materially misleading public statements by TKT about the

status of the FDA application for Replagal. In addition, he sold 90,000 shares of TKT stock while in possession of material non-public information about the negative clinical results and other problems with the FDA application, thereby avoiding losses of more than $1.6 million that he would have incurred had he held the stock until October 2002 when TKT finally disclosed some of the negative information about the application and its stock price dramatically declined.

2. In June 2000, TKT filed an application for FDA approval of Replagal, a treatment for Fabry disease, a rare kidney condition in which patients suffer from extreme pain and kidney dysfunction. From at least October 2000 until it issued corrective disclosure in October 2002, TKT and Selden as CEO made a series of public statements and filed several reports to the Commission describing TKT's most important clinical trial (known as the "pivotal trial") as a success and containing positive statements about Replagal's clinical benefits and chances for FDA approval. However, TKT and Selden as CEO knew but failed to disclose material negative information about Replagal's FDA application such as: (1) the pivotal trial had failed to meet its primary objective; (2) the FDA had informed TKT in January 2001 that the pivotal trial was a failed study and that its primary analysis had failed; (3) the FDA had recommended in January 2001 that TKT conduct additional clinical trials; and (4) TKT had informed the FDA, at least as early as April 2001, that it would no longer seek approval of Replagal based on a claim that the drug was effective against pain.

3. After the market closed on October 2, 2002, TKT publicly announced that the FDA viewed the company's pain-related clinical data as "uninterpretable" and that, as a result, TKT had abandoned its claim that Replagal was clinically effective against pain as a basis for seeking FDA approval. During a conference call with investors that evening, Selden falsely

stated that TKT had only recently learned of the FDA's position and had just decided to change its approach to the application, when in fact the FDA had been communicating negative information to TKT since at least January 2001 and TKT had told the FDA in April 2001 that it was changing its approach. On October 3, 2002, the price of TKT stock plummeted 63% – from a closing price of $33.25 per share on October 2 to $12.75 per share on October 3.

4. Between May 2001 and February 2002, Selden sold 90,000 shares of TKT stock while he knew the material, non-public information about the problems with TKT's clinical trial and its FDA application for Replagal. Based on the closing price of TKT stock after the information was publicly disclosed on October 2, 2002, Selden avoided a loss of $1,664,000 and was unjustly enriched by selling his TKT stock during a period when the stock price was artificially inflated as a result of misleading information in the markets.

5. Through the activities alleged in this Complaint, Selden violated the anti-fraud provisions of the federal securities laws, specifically Section 17(a) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. §77q(a)] and Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5]. Selden also aided and abetted TKT's violations of Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20,13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 & 240.13a-13] by causing TKT to file false and misleading annual, quarterly and other reports with the Commission.

6. Accordingly, the Commission seeks: (a) entry of a permanent injunction prohibiting Selden from further violations of the relevant provisions of the federal securities laws; (b) disgorgement of Selden's ill-gotten gains, plus pre-judgment interest; (c) the imposition

of a civil penalty due to the egregious nature of Selden's violations; and (d) entry of an order barring Selden from serving as an officer or director of a public company.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to Section 22 of the Securities Act [15 U.S.C. §77v] and Sections 21 and 27 of the Exchange Act [15 U.S.C. §§78u & 78aa]. Venue is proper in this District because, at all relevant times, TKT's corporate headquarters was in this District, many of the acts and practices alleged in this Complaint occurred in this District, and Selden lives in this District.

8. The Commission seeks a permanent injunction pursuant to Section 22 of the Securities Act [15 U.S.C. §77v] and Section 21(d)(1) of the Exchange Act [15 U.S.C. §78u(d)(1)]. The Commission seeks the imposition of a civil penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. §77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)]. The Commission seeks an officer and director bar pursuant to Section 20(e) of the Securities Act [15 U.S.C. §77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)].

9. In connection with the conduct described in this Complaint, Selden directly and indirectly made use of the mails or the means or instruments of transportation or communication in interstate commerce.

DEFENDANT AND RELEVANT ENTITY

10. **Selden**, age 46, lives in Wellesley, Massachusetts. He founded TKT and served as its CEO and a director from 1988 until his resignation in February 2003.

11. TKT, a Delaware corporation, is a bio-pharmaceutical company headquartered in Cambridge, Massachusetts. From 1996 through July 2005, TKT common stock was registered with the Commission pursuant to Section 12(g) of the Exchange Act [15 U.S.C. §78l(g)] and traded on the NASDAQ National Market System. Pursuant to Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 13a-1 and 13a-13 thereunder [17 C.F.R. §§240.13a-1 and 240.13a-13], TKT was required to file with the Commission annual reports on Form 10-K and quarterly reports on Form 10-Q. Pursuant to Rule 12b-20 [17 C.F.R. §240.12b-20], TKT's annual and quarterly reports were required to contain such material information as necessary to make the required statements, in the light of the circumstances under which they were made, not misleading. On or about July 28, 2005, TKT was acquired by Shire Pharmaceuticals Group, PLC ("Shire") and became a wholly-owned subsidiary of Shire. As a result, TKT is no longer a publicly-traded company and no longer files periodic reports with the Commission.

STATEMENT OF FACTS

Replagal and its Significance for TKT

12. Replagal is intended to treat Fabry disease, a genetic disorder caused by the lack of a key enzyme. Fabry disease causes extreme pain, particularly in the hands and feet, cloudiness in the cornea of the eye, and hearing loss, and it may involve potentially life-threatening complications such as progressive kidney disease, heart attack, and stroke. The disease is extremely rare, with a U.S. patient population estimated at a few thousand, but treatment for the disease costs approximately $160,000 per patient annually. Replagal has been approved for use in some other countries and, at all relevant times, sales of Replagal abroad were TKT's only source of product revenue. Accordingly, the possibility that the FDA would approve

Replagal for sale within the U.S. was highly material to TKT.

13. In June 2000, TKT submitted an application for FDA approval for domestic sales of Replagal. TKT's application was based upon clinical trials whose principal objective, TKT hoped, was to demonstrate that Replagal had a treatment effect on the extreme pain suffered by patients with Fabry disease. About one week later, Genzyme Corp. ("Genzyme") filed a competing application for its drug, Fabrazyme. Genzyme's application was based upon surrogate marker data, an approach which is generally seen as a less desirable basis for obtaining FDA approval. Both applicants sought "orphan drug" status which, if granted, would result in a seven-year marketing exclusivity within the U.S. The existence of competing orphan drug applications was unprecedented and, because of the "winner-take-all" effect on the first applicant to receive FDA approval, any information about the FDA's attitude toward approval of Replagal would be watched closely by investors. As one analyst described the situation, "It's an amazingly high stakes poker game [TKT] is playing with [Genzyme] – if either company has a glitch in front of the FDA panel, that company may have to wait seven years for another chance."

Replagal's Clinical Trials

14. TKT's pivotal study, called TKT 003, was conducted at the National Institutes of Health. As indicated above, the primary objective or endpoint of the study was to demonstrate that Replagal had a treatment effect on pain. Prior to the study, TKT and the FDA agreed that the primary efficacy analysis (that is, the primary analysis upon which TKT would rely to demonstrate Replagal's clinical benefit for pain) would be an analysis referred to as "area under the curve" or "AUC".

15. The level of confidence in a statistical result is expressed in terms of probability, often known as a "*p* value". Under statistical principles, the smaller the *p* value, the greater the level of certainty that the observed effect was not randomly induced, and a *p* value of 0.05 or less (indicating a 95% level of certainty that the observed effect was not randomly induced) is generally accepted as persuasive. A *p* value higher than 0.05 is not *per se* evidence of failure, but further analysis is needed to assess whether the drug at issue caused the observed effect.

16. In TKT's pivotal study, the *p* value of the AUC analysis for effect on pain was 0.19 – much worse than the desired level of 0.05 or less. Based on this result, the pivotal study failed to meet its primary objective. Subsequent analysis enabled TKT to reduce the asserted *p* value to 0.08, which was still worse than the desired level of 0.05 or less. Although the AUC analysis did not produce a result with a *p* value of 0.05 or lower, two secondary pain analyses yielded *p* values of 0.02 and 0.05, respectively.

May 2000 Meeting with Institutional Investor

17. In May 2000, Selden and other senior TKT executives met privately with an institutional investor who was considering a substantial investment in TKT. At that meeting, Selden and other TKT executives presented the complete results of the pivotal study, including the fact that the one of the *p* values of the AUC analysis was 0.08. Based on the information provided, the investor had sufficient information to conclude in an investment memorandum that the pivotal study had failed to meet its primary objective. Selden also acknowledged to this investor the significant risk that, in light of these results, the FDA would not approve Replagal. After disclosing this negative information to the institutional investor – who was bound by a confidentiality agreement to keep the bad news secret – Selden and TKT embarked upon a

campaign to mislead the investing public about Replagal's chances for FDA approval.

TKT's Misleading Statements at Conference in October 2000

18. In October 2000, TKT representatives made a presentation concerning the pivotal study to medical professionals and investors at a conference sponsored by the American Society of Human Genetics ("ASHG"). TKT's presentation included a slide show, and Selden had reviewed and approved each slide in advance.

19. TKT's presentation described the successful results of the pivotal study with reference to the secondary pain analyses but never mentioned that the primary efficacy analysis (the AUC analysis) had failed to show a benefit (because its *p* value was 0.19). To the contrary, one of the slides purported to show the results of the primary efficacy analysis with a *p* value of 0.02, much better than the desired level of 0.05 or less for demonstrating statistical significance. Although the pivotal study did produce a secondary pain analysis with a *p* value of 0.02, the presentation omitted to say that the *p* value of the primary efficacy analysis was 0.19, much worse than 0.02. Selden had personally decided that TKT's presentation should not include any account of the AUC analysis.

20. TKT's characterization of the pivotal study at the ASHG conference was materially misleading and created the false impression in the investment community that the pivotal study was an unqualified success. For example, one analyst wrote after the conference that "positive pivotal trial results for Replagal were presented at the [ASHG] in October 2000.... Results showed Replagal to be effective in achieving all primary and secondary endpoints, as well as being safe and well-tolerated."

The FDA's Negative January 2, 2001 Review Letter

21. FDA rules require the agency staff to provide a response, known as a "complete review letter", within six months after the filing of an application for approval of a drug. On January 2, 2001, TKT received a complete review letter from the FDA which explicitly stated that TKT had failed to demonstrate the clinical benefits necessary for FDA approval:

> The clinical study data you have provided do not provide substantial evidence of efficacy for [Replagal].... [A]dditional analyses or otherwise revised analyses of the clinical data you have submitted will be unable to address this deficiency. In order to provide substantial evidence of efficacy, we recommend that you conduct additional clinical studies and submit the results to [FDA].

The review letter explained that TKT had failed to demonstrate the efficacy of Replagal or even a statistically significant difference between the trial groups:

> The analysis of the primary endpoint dataset you submitted using the prospectively designed statistical test did not demonstrate a statistically significant difference between treatment groups (p=0.195). Thus, even if this were a valid analysis..., the trial failed to demonstrate efficacy on the prospective primary analysis.

The review letter also offered fundamental criticisms of TKT's handling of the study data:

> [T]he process used to select which values to include in the primary analytical dataset introduced unmeasurable bias and is both inappropriate and unacceptable. We thus conclude that there is no valid analysis of the primary endpoint of TKT003.

22. The January 2, 2001 review letter thus contained a detailed and unequivocal statement by the FDA that TKT's pivotal study was a failure, its methodology was flawed, its primary analysis had not demonstrated a treatment effect on pain with statistical significance, and TKT should conduct additional clinical trials if it hoped to obtain FDA approval for Replagal.

TKT's Misleading January 3, 2001 Press Release

23. On January 3, 2001, after the stock market had closed, TKT issued a press release announcing that the FDA had issued its complete review letter. The same day, TKT filed a current report with the Commission on Form 8-K incorporating the press release. Selden actively participated in drafting the press release, approved the final version of the release, and was quoted in it.

24. The January 3, 2001 press release stated that the FDA had asked for additional data and that TKT employees were working to provide the requested information. The press release was materially misleading because, among other things, it did not disclose that, far from just asking for more information, the FDA had informed TKT that the pivotal study failed to achieve its primary objective and had recommended that TKT conduct additional clinical trials. Even so, market reaction to the release was negative. On January 4, 2001, TKT shares closed at $33.25 per share, down 9% from the previous day's close of $36.56 per share.

25. Within days of the January 2001 press release, a senior executive in charge of clinical trials told Selden that the FDA's recommendation to conduct new studies was important enough to disclose. However, Selden dismissed those concerns, explaining that disclosure was not part of the executive's job, and refused to authorize disclosure of the FDA's recommendation.

26. On January 11, 2001, the FDA's negative view was reaffirmed when TKT's outside counsel spoke with a senior FDA official. The official reiterated the FDA's position that the clinical study was a failure and that the FDA wanted another study.

TKT's Misleading Form 10-K Filed on April 2, 2001

27. On April 2, 2001, TKT filed its annual report on Form 10-K for the year ended December 31, 2000. Selden participated in preparing the Form 10-K, and he signed it as the CEO of TKT.

28. The Form 10-K contained the same statements about the FDA's complete review letter that had appeared in the January 3, 2001 press release, plus some additional generic risk disclosures. These statements were materially misleading because, among other things, they failed to correct TKT's prior misstatements about the results of the clinical trials and because they failed to disclose that, far from just asking for more information, the FDA had informed TKT that its pivotal study was a failure and had recommended that TKT conduct additional clinical trials.

29. The Form 10-K also incorporated by reference the company's annual report to shareholders. The annual report included a letter from Selden concerning the Replagal application which stated that TKT employees "worked to provide the FDA the requested data," as if TKT had already satisfied the FDA's request for more information. This statement was materially misleading because, among other things, it failed to disclose that the FDA had told TKT that its pivotal study was a failure and had recommended that TKT conduct additional clinical trials.

30. In a sidebar appearing on the same page as Selden's letter to shareholders, the annual report stated that positive pivotal clinical results for Replagal demonstrated a reduction in pain, again failing to correct the prior misstatements about the results of the clinical trials and omitting to state that, in the FDA's view, the pivotal study's primary analysis was a failure.

April 26, 2001 Meeting with the FDA

31. On April 26, 2001, Selden and several other TKT executives met with the FDA staff to discuss the complete review letter. At the meeting, the FDA staff again stated that TKT had not demonstrated that Replagal was effective for the pain of Fabry disease and that its pain data was uninterpretable. The senior FDA official again characterized the pivotal study as a "failed study", criticized the results of a six-month follow-up study which TKT had recently submitted, criticized TKT's proposal for a new study because it contained the same design flaws as the pivotal study, and said that TKT needed to come up with other alternatives.

32. The TKT executives responded that the company was no longer going to seek FDA approval for Replagal on the basis of effect on pain. Contemporary writings by Selden and TKT's outside FDA lawyer, including correspondence to the FDA, used words such as "surrender," "moot" and "out of the picture" to describe TKT's proposed change in approach to the FDA application.

33. The remainder of the meeting focused on other ways in which Replagal might be approved. The FDA staff left open the possibility that additional clinical data from a study that had not then been completed, or surrogate marker data of the type being proposed by Genzyme for its competing drug, could lead to approval for Replagal on the basis of a predicted clinical benefit for kidney function. However, the FDA staff made clear that, as the agency had previously informed TKT, the company should not expect approval on the basis of the clinical data already submitted.

TKT's Misleading Form 10-Q Filed on May 14, 2001

34. On May 14, 2001, TKT filed its report on Form 10-Q for the quarter ended March 31, 2001. Selden reviewed and approved the Form 10-Q.

35. When describing the status of the FDA application for Replagal, the Form 10-Q repeated the grossly incomplete characterization of the FDA's complete review letter from the January 2001 press release and the April 2, 2001 Form 10-K, stating only that the FDA "requested further explanation in several areas and additional data." These statements were materially misleading because, besides failing to indicate that the FDA's complete review letter had labeled the pivotal study as a failure, TKT failed to report on the April 26, 2001 meeting, at which the FDA had dismissed the additional data submitted by TKT and questioned the methodology for its proposed new study, and at which TKT had admitted that it was no longer seeking approval for Replagal on the basis that it was effective for pain.

TKT's Misleading May 29, 2001 Press Release

36. On May 29, 2001, TKT issued a press release to publicize an article concerning the pivotal study which had been published in the *Journal of the American Medical Society*. Selden approved the final version of the press release, which had been prepared by TKT's head of investor relations.

37. The press release stated that patients receiving Replagal had a clinically significant reduction in pain. As a result, *Bloomberg* reported on June 5, 2001 that Replagal "markedly relieves pain and improves heart and kidney function."

38. The May 29, 2001 press release was materially misleading because it failed to include at least four critical and negative facts: (1) the *p* value for the pivotal study's primary

analysis was 0.19, much worse than the desired level of 0.05 or less and much worse than the 0.02 figure which TKT had misleadingly presented at the October 2000 ASHG conference; (2) the FDA had stated that the pivotal study was a failure; (3) the FDA had recommended additional clinical trials; and (4) based on the FDA's criticisms of its clinical trial results, TKT had informed the FDA that it was no longer seeking approval for Replagal on the basis of effect on pain.

May 30, 2001 Conference Call with the FDA

39. On or about May 30, 2001, several TKT executives, including Selden, had a conference call with the FDA staff to discuss their continuing review of data submitted by TKT. During this call, the FDA staff reaffirmed their position that TKT's data had failed to demonstrate a treatment effect and again recommended that TKT conduct additional controlled trials.

TKT's Misleading Public Filings from June 2001 through May 2002

40. On June 25, 2001, TKT filed with the Commission a Form 8-K updating its risk disclosure. On June 26, 2001, TKT filed with the Commission a prospectus supplement in connection with a public stock offering. Selden as the CEO of TKT had overall responsibility for both filings.

41. The Form 8-K and prospectus supplement contained similar language concerning Replagal. With respect to the FDA application, the supplement stated:

> The FDA letter stated that the data that we had provided was not adequate for approval of our BLA [Biologic License Application, the formal name for the Replagal application] at the time and requested additional information. In response to this letter, we have discussed our BLA with

> the FDA and have submitted additional data to the FDA. We expect that after the FDA has reviewed our additional data, it will either approve the BLA or decline to approve it. If it declines to approve our BLA, the FDA may request additional information, possibly including data from additional clinical trials.

These statements were materially misleading because, rather than merely requesting additional information, the FDA had explicitly informed TKT that the pivotal study was a failure and had recommended that TKT conduct additional clinical trials, and because, in light of the FDA's negative response, TKT had informed the FDA that it was withdrawing its claims about Replagal's effect on pain and was now relying on the drug's potential impact on kidney function as the basis for obtaining FDA approval.

42. TKT's subsequent public filings in 2001, for which Selden had overall responsibility as CEO, were similarly misleading. In the reports on Form 10-Q which it filed for the quarter ended June 30, 2001 (filed on August 14, 2001) and for the quarter ended September 30, 2001 (filed on November 14, 2001), TKT stated that, according to the FDA's complete review letter, "our BLA was not adequate for final approval action at the time of such letter" and "[t]here can be no assurance as to whether or when [the] application ... will be approved by the relevant regulatory authorities." These statements were materially misleading because, as shown above, Replagal's chances for FDA approval were actually much worse than indicated and TKT had withdrawn the primary basis for its application (Replagal's effect on pain).

43. TKT filed a prospectus and a Form 8-K updating risk disclosures in connection with other stock offerings on December 13, 20 and 21, 2001. These, as well as the Form 10-K for the year ended December 31, 2001 (filed on March 29, 2002), the Form 10-Q for the first

quarter of 2002 (filed on May 15, 2002), and the Form 10-Q for the second quarter of 2002 (filed on August 14, 2002), contained substantially the same disclosure, each of which was materially misleading for the reasons set forth in the preceding two paragraphs. Selden had overall responsibility for these filings as CEO of TKT.

Selden's Misleading Statements to Analysts from Fall 2001 to Spring 2002

44. From the fall of 2001 through the spring of 2002, Selden expressed unfounded optimism and failed to disclose material negative information about the Replagal application in response to direct inquiries from stock market analysts during quarterly conference calls. The question of whether the FDA had recommended new or additional studies was raised repeatedly during these calls. Each time, Selden provided evasive answers which gave the impression that the FDA had not recommended additional studies and that FDA approval on the basis of existing data was likely.

45. For example, in an October 29, 2001 conference call to discuss results of the quarter ended September 30, 2001, an analyst twice asked Selden whether the FDA had suggested additional clinical trials. Selden responded:

> At this point, we think the data that we've provided is already sufficient. And, we have spent a fair amount of time – and continue to spend a fair amount of time – discussing that data. And so, at this point, I don't believe additional trials are going to be required. I can't absolutely rule it out though – I just don't think they'll be required. I think that we have a great data package as it is.

These statements were materially misleading because, among other things, Selden failed to disclose that the *p* value for the primary analysis in the pivotal study was 0.19, much worse than the desired level of 0.05 or less, and that the FDA had repeatedly informed TKT that its trials

were a failure, that TKT should conduct additional clinical trials, and that TKT could not expect approval of Replagal based on the existing data. Further, Selden failed to disclose that, in light of the FDA's continued criticism of its pivotal trial data, TKT had informed the FDA that it was dropping its claim that Replagal was effective on pain and was now seeking approval only on the basis of effect on kidney function, a claim that would require continuing clinical trials. Moreover, these statements were far more optimistic than the negative information which Selden had disclosed to the institutional investor at their confidential meeting back in May 2000, and Replagal's chances for FDA approval had not improved since that meeting.

46. In a February 11, 2002 conference call to discuss year-end results, an analyst asked Selden whether any new trials had been initiated at the request of the FDA. Selden responded that "no trials have been initiated on FDA requirements." This statement was materially misleading for the same reasons cited in the preceding paragraph.

47. In April 2002, the FDA informed TKT that it was willing to consider approving Replagal using "surrogate markers," a form of approval that would require continuing clinical trials in order to demonstrate the clinical benefits that TKT had publicly reported it had achieved. However, the FDA requested substantial additional information, making clear to TKT management that FDA approval was not assured, even on this alternative basis.

48. In a May 2, 2002 conference call with analysts to discuss results for the quarter ended March 31, 2002, Selden optimistically stated, "We believe that the approval of Replagal in the U.S. remains a 'when,' not 'if', proposition." When asked for a more detailed description of the FDA discussions, Selden stated that the conversations with the FDA were very reasonable and were getting better and better. These statements were materially misleading because, among

other things, Selden failed to disclose that the FDA had been telling TKT since January 2001 that Replagal could not be approved based on existing data and that, as recently as April 2002, the FDA had made clear that approval was not assured.

Postponement of the September 2002 Advisory Committee Meeting

49. In early summer 2002, the FDA scheduled an advisory committee meeting for September 26-27, 2002 to review the competing applications by TKT and Genzyme. Such meetings are typically the last step before an FDA decision on approval, and the meetings involve committee members, guests and advisors. Briefing materials are usually posted on the FDA's public Website the day before the meeting.

50. The FDA's briefing materials, consistent with all of their prior statements to TKT, harshly criticized TKT's clinical data, particularly the pain data, as well as TKT's methodology and results, and indicated that the FDA staff could not interpret the pain data submitted and could not draw any conclusions with respect to effect on pain. The FDA materials concluded that the purported kidney benefits of Replagal depended entirely on a "physiologically improbable" change occurring entirely during the 24th week of the study, and that other analyses, including the cardiac data, generally showed no treatment effect.

51. On September 11, 2002, TKT's outside attorney wrote to the FDA alleging that four invited advisory committee guest experts were biased. On September 20, 2002, the FDA abruptly cancelled the meeting. As a result, the FDA's negative briefing materials concerning Replagal were not made public at that time. The advisory committee meeting was later rescheduled for January 15-16, 2003.

Public Disclosure in October 2002

52. At no time prior to October 1, 2002 did TKT inform the public that: (1) the *p* value for the primary analysis in the pivotal study was 0.19, much worse that the desired level of 0.05 level or less and much worse than the 0.02 figure which TKT had misleadingly presented at the October 2000 ASHG conference; (2) the FDA had stated that the pivotal study was a failure; (3) the FDA had recommended additional clinical trials; (4) based on the FDA's criticisms of its clinical pain results, TKT had informed the FDA that it was no longer seeking approval for Replagal on the basis of pain relief; and (5) TKT was now relying solely on Replagal's potential impact on kidney function, an impact to be demonstrated through surrogate marker data instead of proven clinical benefits.

53. On October 2, 2002 – after the stock market closed – TKT issued a press release announcing that the FDA found its pain data to be "uninterpretable" and that TKT had therefore withdrawn its claim that Replagal was effective against pain as a basis for seeking approval of Replagal. A few minutes later, Selden held a conference call with investors. He was repeatedly evasive when asked for further detail about the press release. However, he stated that discussions with the FDA leading to the announcement had occurred only during the past month. He also characterized the change in TKT's strategy for FDA approval as "moderate", asserting that TKT had decided "not to use the pain data as a basis for seeking approval *at this time*" (emphasis added). These statements were false because TKT had actually informed the FDA at least eighteen months earlier (in April 2001) that it was no longer seeking approval based on Replagal's effect on pain.

54. The stock market reacted strongly to TKT's disclosure of the major problems with its FDA application for Replagal. On October 3, 2002, TKT shares closed at $12.75 per share, down 61% from the prior day's close of $33.25 per share. Trading volume on October 3 was 22.8 million shares, whereas trading volume during the preceding month was typically less than 500,000 shares per day.

Subsequent Events

55. On January 15-16, 2003, the FDA advisory committee met to consider TKT's application for Replagal. By a vote of 15-0, the committee rejected the application on the basis of demonstrated clinical results. By a vote of 8-7, the committee rejected the application on the basis of surrogate markers, although the committee held out some prospect that the issue could be revisited with additional analysis. The FDA approved Genzyme's competing application, and Genzyme received a seven-year marketing exclusivity for its drug Fabrazyme.

56. Later in January 2003, the TKT board of directors established a committee to investigate certain management issues, including the handling of the Replagal application. In February 2003, Selden resigned as CEO, although he continued to receive an equivalent salary pursuant to a consulting agreement.

57. On January 12, 2004, TKT announced that it was ending its efforts to seek FDA approval for domestic sales of Replagal.

Selden's Sales of Transkaryotic Shares

58. During 2001 and the first half of 2002 – when he knew that he and TKT had disseminated false and misleading information concerning Replagal to the investing public –

Selden sold tens of thousands of shares of TKT stock.

59. On May 8, 2001, Selden sold 20,000 shares at $22.90 per share. This sale was only two weeks after the April 26, 2001 meeting at which the FDA staff had characterized TKT's pivotal study as a "failed study", had criticized the results of TKT's six-month follow-up study, had criticized TKT's proposal for a new study because of its design flaws, and had stated that TKT needed to come up with other alternatives.

60. On September 20-21, 2001, Selden sold 20,000 shares: 10,000 shares at $24.43 per share and 10,000 shares at $25.05 per share. These sales were one month after TKT had filed a materially misleading Form 10-Q which failed to disclose that the FDA had told TKT that the pivotal trial was a failure and had recommended that TKT conduct additional clinical trials, and which also failed to disclose that, in light of the FDA's negative response, TKT was no longer basing its application on Replagal's effect on pain and was relying instead solely on Replagal's potential impact on kidney function.

61. On November 1, 2001, Selden sold 30,000 shares at $37.07 per share. This sale was one month after TKT had filed another materially misleading Form 10-Q which failed to disclose that the same negative information.

62. On February 14, 2002, Selden sold 20,000 shares at $37.33 per share. This sale was three days after a conference call with analysts in which Selden had once again concealed the FDA's recommendation that TKT conduct additional clinical trials and TKT's decision to withdraw its claim that Replagal had an effect on pain.

63. As demonstrated by the market reaction to the negative information about Replagal that was ultimately disclosed on October 2, 2002, the false and misleading information

previously in the public realm had kept TKT's stock price artificially inflated since at least October 2000. Thus, Selden benefitted by selling TKT shares at artificially inflated prices before the negative news was made public.

64. Based on the closing price of TKT stock after the first day of trading after the negative news had been announced on October 2, 2002, Selden was unjustly enriched in the amount of $1,664,400.

FIRST CLAIM FOR RELIEF
(Violation of Section 10(b) of the Exchange Act and Rule 10b-5)

65. The Commission repeats and realleges paragraphs 1- 64 above.

66. As set forth above, Selden made direct statements to investors and market participants, authorized other TKT employees to make statements to the public concerning Replagal, exercised control over all significant disclosure decisions by TKT, signed TKT's materially misleading Forms 10-K for 2000 and 2001, authorized TKT's offerings of securities using prospectuses that were materially misleading, and offered and sold his own shares to public investors. He knew or was reckless in not knowing that these filings and other public statements were materially misleading because, among other things, they contained false and misleading statements regarding Replagal's clinical results and the FDA application and they omitted material information necessary to make statements made not misleading.

67. By reason of the foregoing, Selden, directly or indirectly, acting intentionally, knowingly or recklessly, by use of the means or instrumentalities of interstate commerce or of the mails, in connection with the purchase or sale of securities: (a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or omitted to state a material fact

necessary to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices or courses of business which operated as a fraud or deceit upon certain persons, including purchasers or sellers of TKT's securities.

68. As a result, Selden violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5], and his violations involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements and resulted in substantial losses or significant risk of substantial losses to other persons, within the meaning of Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)].

SECOND CLAIM FOR RELIEF
(Violation of Section 17(a) of the Securities Act)

69. The Commission repeats and realleges paragraphs 1- 68 above.

70. As set forth above, Selden made direct statements to investors and market participants, authorized other TKT employees to make statements to the public concerning Replagal, exercised control over all significant disclosure decisions by TKT, signed TKT's materially misleading Forms10-K for 2000 and 2001, authorized TKT's offerings of securities using prospectuses that were materially misleading, and offered and sold his own shares to public investors. He knew or was reckless in not knowing that these filings and other public statements were materially misleading because, among other things, they made false and misleading statements regarding Replagal's clinical results and the FDA application, and that material information necessary to make statements made not misleading was omitted.

71. By reason of the foregoing, Selden, directly or indirectly, acting intentionally, knowingly or recklessly, by use of the means or instruments of transportation or communication

in interstate commerce or by the use of the mails, in the offer or sale of securities: (a) employed devices, schemes or artifices to defraud; (b) obtained money or property by means of untrue statements of material fact or omissions to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in transactions, practices or courses of business which operated or would operate as a fraud or deceit upon certain purchasers, including purchasers of TKT's securities.

72. As a result, Selden violated Section 17(a) of the Securities Act [15 U.S.C. §77q(a)], and his violations involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements and directly or indirectly resulted in substantial losses or significant risk of substantial losses to other persons, within the meaning of Section 20(d) of the Securities Act [15 U.S.C. §77t(d)].

THIRD CLAIM FOR RELIEF
(Aiding and Abetting TKT's Violations of
Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13)

73. The Commission repeats and realleges paragraphs 1- 72 above.

74. TKT's annual reports to the Commission on Form 10-K for 2000 and 2001, its quarterly reports to the Commission on Form 10-Q for the first quarter of 2001 through the second quarter of 2002, and certain reports of current events filed as part of Forms 8-K materially misstated facts, and omitted to state material facts necessary to make statements made not misleading, relating to Replagal and the FDA application process. As a result, TKT violated Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 and 240.13a-13].

75. As set forth above, Selden signed certain of TKT's materially misleading filings with the Commission and substantially participated in preparing each of those public filings.

76. By reason of the foregoing, Selden provided knowing and substantial assistance to TKT's filing of materially misleading reports to the Commission.

77. As a result, Selden aided and abetted TKT's violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13.

PRAYER FOR RELIEF

WHEREFORE, the Commission requests that this Court:

A. Enter a permanent injunction restraining Selden and each of his agents, servants, employees and attorneys and those persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in violations of:

1. Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5];

2. Section 17(a) of the Securities Act [15 U.S.C. §77q(a)]; and

3. Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 and 240.13a-13];

B. Order Selden to disgorge all unlawful benefits received, including his unjust enrichment from his sales of TKT shares during the relevant period and, as appropriate, salary, bonus and other compensation received from TKT;

C. Order Selden to pay an appropriate civil penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)];

D. Enter an order, pursuant to Section 20(e) of the Securities Act [15 U.S.C. §77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)], barring Selden from serving as an officer or director of any issuer required to file reports with the Commission pursuant to Sections 12(b), 12(g) or 15(d) of the Exchange Act [15 U.S.C. §§78l(b), 78l(g) and 78o(d)];

E. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

F. Award such other and further relief as the Court deems just and proper.

Respectfully submitted,

Walter G. Ricciardi
District Administrator

Frank C. Huntington (BBO #544045)
Senior Trial Counsel

David E. Butler (BBO #549721)
Senior Enforcement Counsel

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Dated: September 1, 2005

EXHIBIT H

AO88 (Rev. 1/94) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

DISTRICT OF Columbia

Securities and Exchange Commission

V.

Richard B. Selden

SUBPOENA IN A CIVIL CASE

Case Number:[1] 05-11805-NMG (D. Mass.)

TO: Keeper of Records
U.S. Food and Drug Administration
5600 Fishers Lane, Rockville, Maryland 20857

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Skadden, Arps, Slate, Meagher & Flom LLP 1440 New York Avenue, NW, Washington, DC 20005-2111	11/14/2005 10:00 am

☑ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

See Schedule A attached hereto

PLACE	DATE AND TIME
Skadden, Arps, Slate, Meagher & Flom LLP 1440 New York Avenue, NW, Washington, DC 20005-2111	11/28/2005 10:00 am

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
Thomas J. Dougherty / Counsel for Richard B. Selden	10/28/2005

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Thomas J. Dougherty, Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street, Boston, Massachusetts, 02108, Phone No. (617) 573-4800

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

PROOF OF SERVICE

	DATE	PLACE
SERVED	10-31-05 1:50pm	FDA, Office of the Chief Counsel 5600 Fishers Lane, Rockville MD

SERVED ON (PRINT NAME)	MANNER OF SERVICE
Carolyn Burton, Office of Chief Counsel Employee authorized to accept	personally
SERVED BY (PRINT NAME)	**TITLE**
Andre' W. Keith	Process Server

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on 10-31-05
DATE

SIGNATURE OF SERVER

1115 Mass Ave, NW
ADDRESS OF SERVER

Wash, DC 20005

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance,

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the mmmdemanding party to contest the claim.

SCHEDULE A:
DOCUMENTS TO BE PRODUCED

1. All e-mail, memoranda, correspondence, documentation, analyses, communications or other internal documents relating to FDA's consideration, discussion, review or proposals relating to the use of surrogate endpoints for the evaluation or study of Replagal or Fabrazyme.

2. All e-mail, memoranda, correspondence, documentation, analyses, communications or other internal documents relating to FDA's consideration, discussion, review or proposals relating to the issue of dual approval of Replagal or Fabrazyme, whether pursuant to the Orphan Drug Act or otherwise.

3. Every letter issued by CBER, from 1987 to the present, purporting to be "complete Agency actions (for performance goal and review clock purposes) in response to the application or supplement review process." See SOPP 8405.

4. All documents relating to Replagal, gene activated human alpha galactosidase for the treatment of Fabry's disease (hereinafter, "Replagal"), including:

(a) all documents in any electronic form relating to Replagal, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

(b) all documents describing, analyzing or discussing Replagal;

(c) all documents relating to any studies or trials (actual or otherwise) for Replagal;

(d) all documents relating to any endpoints (actual or otherwise) relating to any study or trial for Replagal;

(e) all documents relating to any protocols, statistical analysis plans or clinical study reports relating to Replagal;

(f) all documents relating to any Biologics License Application ("BLA"), Investigational New Drug ("IND"), or any other regulatory submission for Replagal;

(g) all communications between the FDA any other governmental agency, body, or entity, relating to Replagal;

(h) all communications between the FDA and the SEC relating to Replagal;

(i) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to Replagal;

(j) all documents issued, distributed, published, circulated or otherwise made available to the public relating to Replagal;

(k) all documents, including any correspondence, reports, presentations, memoranda, notes, drafts, diagrams and e-mails, relating to any research projects, studies, or cost analysis conducted, initiated or funded by the United States, relating to Replagal.

(l) all documents relating to Replagal that are not physically located at the FDA but which the FDA has possession, custody or control;

(m) all documents relating to Replagal in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Conner, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(n) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(o) all other documents relating to Replagal not already requested in ¶¶ 1(a)-(n), above.

5. All documents relating to TKT, including:

(a) all documents in any electronic form relating to TKT, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

(b) all documents describing, analyzing or discussing TKT;

(c) all documents relating to any studies or trials (actual or otherwise) by or on behalf of TKT;

(d) all documents relating to any endpoints (actual or otherwise) relating to any study or trial by or on behalf of TKT;

(e) all documents relating to any protocols, statistical analysis plans or clinical study reports by or on behalf of TKT;

(f) all documents relating to any BLA, IND, or any other regulatory submission by or on behalf of TKT;

(g) all communications between the FDA any other governmental agency, body, or entity, relating to TKT;

(h) all communications between the FDA and the SEC relating to TKT;

(i) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to TKT;

(j) all documents issued, distributed, published, circulated or otherwise made available to the public relating to TKT;

(k) all documents, including any correspondence, reports, presentations, memoranda, notes, drafts, diagrams and e-mails, relating to any research projects, studies, or cost analysis conducted, initiated or funded by the United States (including the FDA), relating to TKT.

(l) all documents relating to TKT that are not physically located at the FDA but which the FDA has possession, custody or control;

(m) all documents relating to TKT in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Connor, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(n) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(o) all other documents relating to Replagal not already requested in ¶¶ 2(a)-(n), above.

6. All documents relating to Dr. Selden, including:

(a) all documents in any electronic form relating to Dr. Selden, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

(b) all documents describing or discussing Dr. Selden;

(c) all communications between the FDA any other governmental agency, body, or entity, relating to Dr. Selden;

(d) all communications between the FDA and the SEC relating to Dr. Selden;

(e) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to Dr. Selden;

(f) all documents issued, distributed, published, circulated or otherwise made available to the public relating to Dr. Selden;

(g) all documents relating to Dr. Selden that are not physically located at the FDA but which the FDA has possession, custody or control;

(h) all documents relating to Dr. Selden in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Connor, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(i) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(j) all other documents relating to Dr. Selden not already requested in ¶¶ 3(a)-(i), above.

7. All documents generated up through and including April 24, 2003, relating to Fabrazyme, recombinant human alpha galactosidase for the treatment of Fabry's disease (hereinafter, "Fabrazyme"), including:

(a) the letter sent to Genzyme on or about December 22, 2000 (sometimes know as the "complete response letter"), relating to Fabrazyme;

(b) all documents in any electronic form relating to Fabrazyme, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

(c) all documents describing, analyzing or discussing Fabrazyme;

(d) all documents relating to any studies or trials (actual or otherwise) for Fabrazyme;

(e) all documents relating to any endpoints (actual or otherwise) relating to any study or trial for Fabrazyme;

(f) all documents relating to any protocols, statistical analysis plans or clinical study reports relating to Fabrazyme;

(g) all documents relating to any BLA, IND, or any other regulatory submission for Fabrazyme;

(h) all communications between the FDA any other governmental agency, body, or entity, relating to Fabrazyme;

(i) all communications between the FDA and the SEC relating to Fabrazyme;

(j) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to Fabrazyme;

(k) all documents issued, distributed, published, circulated or otherwise made available to the public relating to Fabrazyme;

(l) all documents, including any correspondence, reports, presentations, memoranda, notes, drafts, diagrams and e-mails, relating to any research projects, studies, or cost analysis conducted, initiated or funded by the United States, relating to Fabrazyme.

(m) all documents relating to Fabrazyme that are not physically located at the FDA but which the FDA has possession, custody or control;

(n) all documents relating to Fabrazyme in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Connor, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(o) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(p) all other documents relating to Fabrazyme not already requested in ¶¶ 4(a)-(o), above.

8. All documents relating to this lawsuit and any other lawsuit involving TKT or Replagal, whether concluded, pending, or contemplated.

9. All guidelines, policies, manuals and instructions applied by CBER relating to the review of BLAs, INDs or any contemplated, proposed, on-going or completed trial, study, protocol or statistical analysis plan.

10. All standard record retention schedules maintained pursuant to which existing FDA records are subject to routine destruction as described in 20 C.F.R. 20.23(c).

11. All documents, including any correspondence, reports, presentations, memoranda, notes, drafts, diagrams and e-mails, relating to the dissolution of, or potential dissolution of CBER.

12. Any proposed or final guidelines, protocols, FAQ's or other advisories for the information or assistance of those making public disclosures of the status of a drug biologics application approval or denial by the FDA.

13. All documents relating to the joint FDA/SEC effort to increase the public's protection from false and misleading statements by enhancing inter-agency cooperation.

DEFINITIONS AND INSTRUCTIONS

Richard Selden incorporates by reference the Uniform Definitions In Discovery Subpoenas as set forth in United States District Court for the District of Massachusetts Local Rule 26.5.

Additionally, the following definitions and instructions shall apply:

(A) "CBER" includes the Center for Biologics Evaluation and Research and each of its officers, employees, agents, representatives or attorneys, or any individual or entity presently or formerly acting at their request or on their behalf.

(B) "CDER" includes the Center for Drug Evaluation and Research and each of its officers, employees, agents, representatives or attorneys, or any individual or entity presently or formerly acting at their request or on their behalf.

(C) The "FDA" includes the U.S. Food & Drug Administration, and its departments, including but not limited to the Center for Biologics Evaluation and Research ("CBER"), any FDA employee, staff, consultant, agent, or any other member, guest or other person invited to advise the FDA relating to Replagal or Fabrazyme.

(D) "Genzyme" includes Genzyme Corp., and its parents, successors, subsidiaries, divisions, operating units, affiliates, principals, officers, directors, employees, agents, attorneys, independent contractors and any person acting on their behalf.

(E) "Richard Selden" or "Dr. Selden" includes Richard F. Selden, his employees, representatives, agents, attorneys and all other persons or entities acting or purporting to act on his behalf.

(F) The "SEC" includes the United States Securities and Exchange Commission, and each of its officers, employees, agents, representatives or attorneys, or any individual or entity presently or formerly acting at their request or on their behalf.

(G) "TKT" includes Transkaryotic Therapies, Inc., and its parents, successors, subsidiaries, divisions, operating units, affiliates, principals, officers, directors, employees, agents, attorneys, independent contractors and any person acting on their behalf.

(H) The "United States" includes the United States federal government and each of its agencies, including the FDA, and each of its officers, employees, agents, representatives or attorneys, or any individual or entity presently or formerly acting at their request or on their behalf.

(I) The term "Replagal" refers to agalsidase alfa, a niche protein product program created by TKT for enzyme replacement therapy for the treatment of Fabry disease and for which TKT filed a BLA with the FDA in June 2000.

(J) The term "communication" is used in the broadest sense and means the transmittal of information (in the form of facts, ideas, inquiries or otherwise) whether written or oral, and includes without limitation all forms of electronic mail, voice mail or other recorded

forms of communication. It includes, but is not limited to, documents, meetings and conversations. To the extent the communication is a meeting or conversation, you are requested to (a) identify all participants in the meeting or conversation, and (b) state the nature and substance of the meeting or conversation. The term "communications" means yes transmittal of information (in the form of facts, ideas, inquiries or otherwise).

(K) The term "document" is used in the broadest sense and includes, but is not limited to, the following items, whether typed, printed, recorded, written out by hand, photographed, microfilmed, microfiched, or reproduced by any other mechanical or electronic process, including any information maintained on computer memory disk or electronic or magnetic media, whether or not printed out, and any information to which you have access by reason of any computer, including, without limitation: agreements; contracts; communications, including intra-company communications; correspondence; e-mails; envelopes; telegrams; telecopies; telefacsimiles; memoranda; agenda; books; summaries of records of personal or telephone conversations or interviews; telephone logs, diaries; articles; newspapers; circulars; brochures; pamphlets; forecasts; statistical statements; accountants; work papers; graphs; charts; slides; drawings; diagrams; films; video tapes; visual aids; audio tapes; compact discs or CD-ROMs; accounts; analytical records; worksheets; worksheet files; spreadsheets; word processor files; minutes or records of meetings or conferences; reports or summaries of interviews; reports or summaries of investigations; opinions or reports of consultants; appraisals' records; reports or summaries of negotiations; trade letters; press releases; notes; projections; drafts of any documents; working papers; securities ledgers; checks, front and back; check stubs or receipts; including any other document or writings of whatever description.

(L) The term "person" includes natural persons, or any business, legal, or governmental entity or association.

(M) The term "relating to" means concerning, constituting, containing, embodying, comprising, reflecting, identifying, stating, referring to, dealing with, commenting on, responding to, describing, analyzing, or in any way pertaining to.

(N) The singular includes the plural and the plural includes the singular; the words "and" and "or" shall be both conjunctive and disjunctive; "any" means "any and all"; the word "include" or "including" means including without limitation.

(O) Each request for documents seeks production of the document in its entirety, without abbreviation or expurgation, including all attachments or other matters affixed thereto.

(P) If any document covered by this Subpoena is withheld by reason of a claim of privilege or exemption, a list is to be furnished at the time that documents are produced identifying any such documents for which the privilege is claimed together with the following information with respect to any such document withheld: date, sender, recipient, any person to whom copies were furnished and the identity of any person, general subject matter, basis on which privilege is claimed and the paragraph of this Subpoena to which such document relates.

(Q) In the event that any document called for by this Subpoena has been destroyed, lost, discarded or otherwise disposed of within the twelve months preceding the date of this Subpoena, any such document is to be identified as completely as possible, including, without

limitation, the following information: date of disposal, manner of disposal, reason for disposal, person authorizing the disposal and person disposing of the document.

(R) If you have any objections to this Subpoena, a written statement containing those objections is to be furnished at the time specified herein for the production of documents.

(S) Pursuant to Rule 26(e) of the Federal Rules of Civil Procedure, this Subpoena shall be deemed continuing so as to require further and supplemental production if the FDA or the Center for Biologics Evaluation and Research obtains or discovers additional documents between the time of initial production and the time of hearing or trial.

(T) All documents are to be produced as they are kept in the usual course of business so that Dr. Selden can ascertain the file in which they are located, their relative order in such files and how such files were maintained.

EXHIBIT I

AO88 (Rev. 1/94) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

DISTRICT OF Columbia

Securities and Exchange Commission

V.

Richard B. Selden

SUBPOENA IN A CIVIL CASE

Case Number:[1] 05-11805-NMG (D. Mass.)

TO: Keeper of Records
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration
1401 Rockville Pike, Rockville, Maryland 20852-1448

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☑ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION	DATE AND TIME
Skadden, Arps, Slate, Meagher & Flom LLP 1440 New York Avenue, NW, Washington, DC 20005-2111	11/14/2005 2:00 pm

☑ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):

See Schedule A attached hereto

PLACE	DATE AND TIME
Skadden, Arps, Slate, Meagher & Flom LLP 1440 New York Avenue, NW, Washington, DC 20005-2111	11/28/2005 10:00 am

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE
Thomas J. Dougherty, Counsel for Richard Selden	10/28/2005

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Thomas J. Dougherty, Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street, Boston, Massachusetts, 02108, Phone No. (617) 573-4800

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

PROOF OF SERVICE

	DATE	PLACE
SERVED	10-31-05 1:50pm	FDA, Office of the Chief Counsel 5600 Fishers Lane, Rockville, MD

SERVED ON (PRINT NAME)	MANNER OF SERVICE
Carolyn Burton, Office of Chief Counsel Employee authorized to accept	personally

SERVED BY (PRINT NAME)	TITLE
Andre' W. Keith	process Server

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on 10-31-05
DATE

SIGNATURE OF SERVER

4115 Mass. Ave, NW
ADDRESS OF SERVER

Wash, DC 20005

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to comply production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

(i) fails to allow reasonable time for compliance,

(ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in who behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the mmmdemanding party to contest the claim.

SCHEDULE A:
DOCUMENTS TO BE PRODUCED

1. All e-mail, memoranda, correspondence, documentation, analyses, communications or other internal documents relating to FDA's consideration, discussion, review or proposals relating to the use of surrogate endpoints for the evaluation or study of Replagal or Fabrazyme.

2. All e-mail, memoranda, correspondence, documentation, analyses, communications or other internal documents relating to FDA's consideration, discussion, review or proposals relating to the issue of dual approval of Replagal or Fabrazyme, whether pursuant to the Orphan Drug Act or otherwise.

3. Every letter issued by CBER, from 1987 to the present, purporting to be "complete Agency actions (for performance goal and review clock purposes) in response to the application or supplement review process." See SOPP 8405.

4. All documents relating to Replagal, gene activated human alpha galactosidase for the treatment of Fabry's disease (hereinafter, "Replagal"), including:

(a) all documents in any electronic form relating to Replagal, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

(b) all documents describing, analyzing or discussing Replagal;

(c) all documents relating to any studies or trials (actual or otherwise) for Replagal;

(d) all documents relating to any endpoints (actual or otherwise) relating to any study or trial for Replagal;

(e) all documents relating to any protocols, statistical analysis plans or clinical study reports relating to Replagal;

(f) all documents relating to any Biologics License Application ("BLA"), Investigational New Drug ("IND"), or any other regulatory submission for Replagal;

(g) all communications between the FDA any other governmental agency, body, or entity, relating to Replagal;

(h) all communications between the FDA and the SEC relating to Replagal;

(i) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to Replagal;

(j) all documents issued, distributed, published, circulated or otherwise made available to the public relating to Replagal;

(k) all documents, including any correspondence, reports, presentations, memoranda, notes, drafts, diagrams and e-mails, relating to any research projects, studies, or cost analysis conducted, initiated or funded by the United States, relating to Replagal.

(l) all documents relating to Replagal that are not physically located at the FDA but which the FDA has possession, custody or control;

(m) all documents relating to Replagal in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Conner, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(n) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(o) all other documents relating to Replagal not already requested in ¶¶ 1(a)-(n), above.

5. All documents relating to TKT, including:

(a) all documents in any electronic form relating to TKT, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

(b) all documents describing, analyzing or discussing TKT;

(c) all documents relating to any studies or trials (actual or otherwise) by or on behalf of TKT;

(d) all documents relating to any endpoints (actual or otherwise) relating to any study or trial by or on behalf of TKT;

(e) all documents relating to any protocols, statistical analysis plans or clinical study reports by or on behalf of TKT;

(f) all documents relating to any BLA, IND, or any other regulatory submission by or on behalf of TKT;

(g) all communications between the FDA any other governmental agency, body, or entity, relating to TKT;

(h) all communications between the FDA and the SEC relating to TKT;

(i) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to TKT;

(j) all documents issued, distributed, published, circulated or otherwise made available to the public relating to TKT;

(k) all documents, including any correspondence, reports, presentations, memoranda, notes, drafts, diagrams and e-mails, relating to any research projects, studies, or cost analysis conducted, initiated or funded by the United States (including the FDA), relating to TKT.

(l) all documents relating to TKT that are not physically located at the FDA but which the FDA has possession, custody or control;

(m) all documents relating to TKT in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Connor, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(n) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(o) all other documents relating to Replagal not already requested in ¶¶ 2(a)-(n), above.

6. All documents relating to Dr. Selden, including:

(a) all documents in any electronic form relating to Dr. Selden, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

(b) all documents describing or discussing Dr. Selden;

(c) all communications between the FDA any other governmental agency, body, or entity, relating to Dr. Selden;

(d) all communications between the FDA and the SEC relating to Dr. Selden;

(e) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to Dr. Selden;

(f) all documents issued, distributed, published, circulated or otherwise made available to the public relating to Dr. Selden;

(g) all documents relating to Dr. Selden that are not physically located at the FDA but which the FDA has possession, custody or control;

(h) all documents relating to Dr. Selden in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Connor, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(i) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(j) all other documents relating to Dr. Selden not already requested in ¶¶ 3(a)-(i), above.

7. All documents generated up through and including April 24, 2003, relating to Fabrazyme, recombinant human alpha galactosidase for the treatment of Fabry's disease (hereinafter, "Fabrazyme"), including:

(a) the letter sent to Genzyme on or about December 22, 2000 (sometimes know as the "complete response letter"), relating to Fabrazyme;

(b) all documents in any electronic form relating to Fabrazyme, including all e-mail, computer hard drives, documents on any form of network, deleted electronic documents, DVDs, CDs, tape or other backup, storage or archive systems;

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(f) all documents relating to any protocols, statistical analysis plans or clinical study reports relating to Fabrazyme;

(g) all documents relating to any BLA, IND, or any other regulatory submission for Fabrazyme;

(h) all communications between the FDA any other governmental agency, body, or entity, relating to Fabrazyme;

(i) all communications between the FDA and the SEC relating to Fabrazyme;

(j) all communications between the FDA and any individual or entity not employed by or part of a governmental agency, body or entity, relating to Fabrazyme;

(k) all documents issued, distributed, published, circulated or otherwise made available to the public relating to Fabrazyme;

(l) all documents, including any correspondence, reports, presentations, memoranda, notes, drafts, diagrams and e-mails, relating to any research projects, studies, or cost analysis conducted, initiated or funded by the United States, relating to Fabrazyme.

(m) all documents relating to Fabrazyme that are not physically located at the FDA but which the FDA has possession, custody or control;

(n) all documents relating to Fabrazyme in the possession, custody or control (or at any time previously in the possession, custody or control) of Beverly Connor, Bradley Glasscock, John Hill, Dwaine Rieves, Amy Rosenberg, Jay Siegel, Linda Skiadany, Dan Troy, Marc Walton or Karen Weiss;

(o) any reports, presentations, memoranda, notes, drafts, diagrams, memoranda, minutes, communications, correspondence, discussions, briefings, agendas or analyses relating to any of the above; and

(p) all other documents relating to Fabrazyme not already requested in ¶¶ 4(a)-(o), above.

8. All documents relating to this lawsuit and any other lawsuit involving TKT or Replagal, whether concluded, pending, or contemplated.

9. All guidelines, policies, manuals and instructions applied by CBER relating to the review of BLAs, INDs or any contemplated, proposed, on-going or completed trial, study, protocol or statistical analysis plan.

10. All standard record retention schedules maintained pursuant to which existing FDA records are subject to routine destruction as described in 20 C.F.R. 20.23(c).

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12. Any proposed or final guidelines, protocols, FAQ's or other advisories for the information or assistance of those making public disclosures of the status of a drug biologics application approval or denial by the FDA.

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(B) "CDER" includes the Center for Drug Evaluation and Research and each of its officers, employees, agents, representatives or attorneys, or any individual or entity presently or formerly acting at their request or on their behalf.

(C) The "FDA" includes the U.S. Food & Drug Administration, and its departments, including but not limited to the Center for Biologics Evaluation and Research ("CBER"), any FDA employee, staff, consultant, agent, or any other member, guest or other person invited to advise the FDA relating to Replagal or Fabrazyme.

(D) "Genzyme" includes Genzyme Corp., and its parents, successors, subsidiaries, divisions, operating units, affiliates, principals, officers, directors, employees, agents, attorneys, independent contractors and any person acting on their behalf.

(E) "Richard Selden" or "Dr. Selden" includes Richard F. Selden, his employees, representatives, agents, attorneys and all other persons or entities acting or purporting to act on his behalf.

(F) The "SEC" includes the United States Securities and Exchange Commission, and each of its officers, employees, agents, representatives or attorneys, or any individual or entity presently or formerly acting at their request or on their behalf.

(G) "TKT" includes Transkaryotic Therapies, Inc., and its parents, successors, subsidiaries, divisions, operating units, affiliates, principals, officers, directors, employees, agents, attorneys, independent contractors and any person acting on their behalf.

(H) The "United States" includes the United States federal government and each of its agencies, including the FDA, and each of its officers, employees, agents, representatives or attorneys, or any individual or entity presently or formerly acting at their request or on their behalf.

(I) The term "Replagal" refers to agalsidase alfa, a niche protein product program created by TKT for enzyme replacement therapy for the treatment of Fabry disease and for which TKT filed a BLA with the FDA in June 2000.

(J) The term "communication" is used in the broadest sense and means the transmittal of information (in the form of facts, ideas, inquiries or otherwise) whether written or oral, and includes without limitation all forms of electronic mail, voice mail or other recorded

forms of communication. It includes, but is not limited to, documents, meetings and conversations. To the extent the communication is a meeting or conversation, you are requested to (a) identify all participants in the meeting or conversation, and (b) state the nature and substance of the meeting or conversation. The term "communications" means yes transmittal of information (in the form of facts, ideas, inquiries or otherwise).

(K) The term "document" is used in the broadest sense and includes, but is not limited to, the following items, whether typed, printed, recorded, written out by hand, photographed, microfilmed, microfiched, or reproduced by any other mechanical or electronic process, including any information maintained on computer memory disk or electronic or magnetic media, whether or not printed out, and any information to which you have access by reason of any computer, including, without limitation: agreements; contracts; communications, including intra-company communications; correspondence; e-mails; envelopes; telegrams; telecopies; telefacsimiles; memoranda; agenda; books; summaries of records of personal or telephone conversations or interviews; telephone logs, diaries; articles; newspapers; circulars; brochures; pamphlets; forecasts; statistical statements; accountants; work papers; graphs; charts; slides; drawings; diagrams; films; video tapes; visual aids; audio tapes; compact discs or CD-ROMs; accounts; analytical records; worksheets; worksheet files; spreadsheets; word processor files; minutes or records of meetings or conferences; reports or summaries of interviews; reports or summaries of investigations; opinions or reports of consultants; appraisals' records; reports or summaries of negotiations; trade letters; press releases; notes; projections; drafts of any documents; working papers; securities ledgers; checks, front and back; check stubs or receipts; including any other document or writings of whatever description.

(L) The term "person" includes natural persons, or any business, legal, or governmental entity or association.

(M) The term "relating to" means concerning, constituting, containing, embodying, comprising, reflecting, identifying, stating, referring to, dealing with, commenting on, responding to, describing, analyzing, or in any way pertaining to.

(N) The singular includes the plural and the plural includes the singular; the words "and" and "or" shall be both conjunctive and disjunctive; "any" means "any and all"; the word "include" or "including" means including without limitation.

(O) Each request for documents seeks production of the document in its entirety, without abbreviation or expurgation, including all attachments or other matters affixed thereto.

(P) If any document covered by this Subpoena is withheld by reason of a claim of privilege or exemption, a list is to be furnished at the time that documents are produced identifying any such documents for which the privilege is claimed together with the following information with respect to any such document withheld: date, sender, recipient, any person to whom copies were furnished and the identity of any person, general subject matter, basis on which privilege is claimed and the paragraph of this Subpoena to which such document relates.

(Q) In the event that any document called for by this Subpoena has been destroyed, lost, discarded or otherwise disposed of within the twelve months preceding the date of this Subpoena, any such document is to be identified as completely as possible, including, without

limitation, the following information: date of disposal, manner of disposal, reason for disposal, person authorizing the disposal and person disposing of the document.

(R) If you have any objections to this Subpoena, a written statement containing those objections is to be furnished at the time specified herein for the production of documents.

(S) Pursuant to Rule 26(e) of the Federal Rules of Civil Procedure, this Subpoena shall be deemed continuing so as to require further and supplemental production if the FDA or the Center for Biologics Evaluation and Research obtains or discovers additional documents between the time of initial production and the time of hearing or trial.

(T) All documents are to be produced as they are kept in the usual course of business so that Dr. Selden can ascertain the file in which they are located, their relative order in such files and how such files were maintained.

EXHIBIT J

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

NOV 12 2005

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

November 9, 2005

VIA FACSIMILE AND U.S. MAIL
617-573-4822

Thomas J. Dougherty
Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street
Boston, MA 02108

Re: Securities and Exchange Commission v. Richard B. Seldon
Civil Action No. 05-11805-NMG

Dear Mr. Dougherty:

I write on behalf of the United States Food and Drug Administration ("FDA") in response to the subpoenas for testimony and documents directed to the Records Custodian of FDA and the Records Custodian of the FDA Center for Biologics Evaluation and Research, both dated October 28, 2005. For the reasons discussed below, FDA, a non-party in the above-referenced action, objects to the subpoenas and requests that they be withdrawn.

First, FDA cannot be compelled to testify or produce records in response to a subpoena issued pursuant to Rule 45 of the Federal Rules of Civil Procedure. Rule 45 provides, in part, that "[e]very subpoena shall . . . command each person to whom it is directed to attend and give testimony or to produce and permit inspection and copying of designated . . . documents." Fed. R. Civ. P. 45(a)(1)(C). The Supreme Court has consistently held that, as a matter of plain meaning, "the term 'person' does not include the sovereign, [and] statutes employing the [word] are ordinarily construed to exclude [the government]." Will v. Mich. Dep't of State Police, 491 U.S. 58, 64 (1989) (first two alterations in original) (citation omitted); see also Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765, 780-81 (2000). Lower courts have therefore held that a subpoena issued pursuant to Rule 45 may not be used to seek discovery from an agency of the federal government because the term "person" as used in that Rule does not include the federal government. See Yousuf v. Samantar, No. 05-110, 2005 U.S. Dist. LEXIS 8488, at *14 (D.D.C. May 3, 2005) (holding that Rule 45 cannot be used to compel the federal government to produce documents when the government is not a party to the case); United States ex rel. Taylor v. Gabelli, No. 04-534, 2005 U.S. Dist. LEXIS 8489, at *7 (D.D.C. May 2, 2005) stating that "the term 'person' in Rule 45, in the absence of a satisfactory basis to override this interpretive presumption [that 'person' excludes the sovereign], does not include the federal government"); Lerner v. District of Columbia, No. 00-1590, 2005 U.S. Dist. LEXIS 10154, at *17 (D.D.C. Jan. 7, 2005) (finding that the court lacked jurisdiction to subpoena the federal

government because "the 'requisite affirmative indications' that the term 'person' in Rule 45 includes the federal government are absent"); see also Al-Fayed v. CIA, 229 F.3d 272, 276-77 (D.C. Cir. 2000) (affirming the district court's quashing of a subpoena issued under 28 U.S.C. § 1782 because there was no "affirmative evidence to disturb the presumption that 'person' excludes the sovereign").

Second, the subpoena does not comply with the criteria set forth in FDA's regulations, 21 C.F.R. part 20, governing requests for the testimony of FDA employees. These regulations describe the procedures that must be followed when non-government parties, such as the plaintiff in the above-referenced action, request testimony from an officer or employee of FDA. The regulations specifically prohibit officers and employees of FDA from testifying about FDA functions or information acquired in the discharge of their official duties. 21 C.F.R. § 20.1(a). Any person who desires testimony from an FDA employee must submit a written request to the Commissioner in accordance with the procedures set forth in 21 C.F.R. § 20.1(c). Both the Supreme Court and the United States Court of Appeals for the Fourth Circuit have held that under the principles of sovereign immunity, an administrative agency may promulgate regulations that limit the extent to which demands for the testimony of agency employees and documents will be honored in civil litigation in which the agency is not a party. See United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951); COMSAT Corp. v. Nat'l Sci. Found., 190 F.3d 269, 278 (4th Cir. 1999); Boron Oil Co. v. Downie, 873 F.2d 67, 71 (4th Cir. 1989).

Third, even if FDA could properly be compelled to give testimony in response to a subpoena issued pursuant to Rule 45, the agency objects to the subpoena on the following grounds:

(1) The subpoena may require disclosure of information that is or contains proprietary, trade secret, confidential commercial, personal privacy, investigatory, pre-decisional, and/or agency deliberative process information that is protected from disclosure under the applicable laws, regulations, or privileges.

(2) The subpoena is unduly burdensome and over broad, particularly in that it requests documents that are more than 18 years old. In order to fully respond to the subpoena, the agency would have to search for and obtain old documents from federal records storage areas and retrieve e-mails from computer archives. Therefore, compliance with this subpoena would require an unreasonable commitment of agency resources.

(3) The subpoena is unduly burdensome in that it requests documents that are publically available in an electronic format on the internet.

(4) The subpoena fails to allow reasonable time for the agency to comply.

Without waiving any of the objections above, I am available to discuss with you other avenues for obtaining information from the agency. Please feel free to contact me at (301) 827-9572.

Sincerely,

Jennifer Zachary
Trial Counsel
Office of Chief Counsel
U.S. Food and Drug Administration

cc: Justin J. Daniels, Skadden, Arps, Slate, Meagher & Flom LLP
Anne P. Smith, Testimony Specialist, FDA

EXHIBIT K

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VIENNA

November 15, 2005

BY FACSIMILE AND U.S. MAIL

Jennifer Zachary
Trial Counsel
Office of Chief Counsel
U.S. Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

Re: SEC v. Richard F. Selden
Civil Action No. 05-11805-NMG (D. Mass.)

Dear Ms. Zachary:

This responds to your letter of November 9, 2005, in which you convey the U.S. Food and Drug Administration's ("FDA's") position that it will not comply in any respect with the October 31, 2005 federal subpoenas for documents and testimony served by Richard F. Selden ("Defendant") in the above-referenced matter. For the reasons set forth below, and in light of the specific circumstances of this case, we believe that the FDA's refusal to comply with the subpoenas in this matter is improper, unauthorized, and should be reconsidered.

Background

This is a federal securities fraud action brought by the SEC against Dr. Richard F. Selden, the founder and former President and Chief Executive Officer of Transkaryotic Therapies, Inc. ("TKT"), in connection with the FDA's review for domestic marketing approval of Replagal, TKT's drug for the treatment of Fabry Disease.[1] The lawsuit alleges that Dr. Selden, in connection with his duties as CEO of TKT, is responsible for a "series of [allegedly] materially misleading public statements

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1 Although Replagal is approved in over 34 countries around the world (including the countries of the European Union, Australia and Canada), in January 2004, TKT dropped its effort to obtain FDA approval of Replagal in the United States.

by TKT about the status of the FDA application for Replagal." See Complaint ¶ 1 (attached hereto at Tab A). One need only review the Complaint to see that the heart of the SEC's case addresses the FDA's views about Replagal and the steps needed for TKT to obtain U.S. approval. See, e.g., id. ¶¶ 2, 3, 4, 12, 13, 14, 21, 22, 24, 25, 26, 28, 29, 30, 31, 32, 33, 35, 38, 39, 41, 42, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 55, 59, 60, 62, 66, 70 & 74.

Not surprisingly, therefore, a focal point of the SEC's investigation for the last three years leading up to this lawsuit has been the SEC's effort to collect materials and information from the FDA. Based on the limited information we have been provided to date by the SEC, it is clear that from the very beginning, the FDA has been cooperating extensively with the SEC in the SEC's effort in this regard.[2] Among other events we have recently learned of are the following:

- On October 22, 2002, or approximately three weeks after when we believe the SEC commenced its investigation, the SEC sent a request for materials to the FDA in the form of an "access letter." (The SEC did not provide us with a copy of this letter; however, it is referred to in subsequent FDA-SEC communications, see Tab B, attached hereto.)

- On November 18, 2002, the FDA provided the first of several subsequent productions of documents to the SEC. The FDA's production included internal FDA electronic mail concerning TKT and Replagal.

- On January 23, 2003, the FDA produced more materials to the SEC.

- On February 10, 2003, the SEC sent another request for materials to the FDA, seeking additional non-public information pursuant to 21 C.F.R. § 20.85 ("Disclosure to other Federal government

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[2] In fact, the agency began working with the SEC even before the FDA had concluded its regulatory review of TKT's biologics license application for Replagal.

departments and agencies").[3] (See Tab B, attached hereto.)

- On May 15, 2003, the SEC sent copies of press releases to the FDA relating to the SEC's investigation of TKT. (See Tab C, attached hereto.)

- On May 28, 2003, the FDA provided additional documents to the SEC. (See Tab D, attached hereto.)

- On May 30, 2003, with the knowledge of the FDA General Counsel's Office, the SEC conducted an informal interview of Dr. Marc K. Walton of the FDA, one of the reviewers of TKT's biologics application for Replagal. We have no evidence of FDA authorization of the interview. We also have been provided with no information about the substance of the interview. (See Tab E, attached hereto.)

- On June 25, 2003, the SEC sought the formal testimony from Dr. Walton pursuant to 21 C.F.R. § 20.1, et seq. (The SEC did not provide us with a copy of this letter; however, it is referred to in subsequent FDA-SEC communications, see Tab F, attached hereto.)

- On June 26, 2003, the FDA responded to the SEC's request for Dr. Walton's testimony. The FDA authorized the testimony "[i]n keeping with our policy of assisting other government agencies in

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[3] As revised April 1, 2002, 21 C.F.R. § 20.85, states that: "Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets and confidential commercial or financial information prohibited from disclosure by 21 U.S.C. 331(j), 21 U.S.C. 360(j)(c), 42 U.S.C. 263g(d) and 42 U.S.C. 263i(e) may be released only as provided by those sections. Any disclosure under this section shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration."

> matters related to the protection of the public health."

- On July 22, 2003, Dr. Walton gave sworn testimony to the SEC. Neither Dr. Selden nor his counsel were notified of the testimony at the time.

In sum, the FDA is far from a bystander to this action. It has been involved from very early on and has extensively cooperated with the SEC in its investigation, supplying non-public documents, informal ("off-the-record") interviews, as well as sworn testimony from the same key witness.

The FDA's Arguments Against The Subpoenas

Against this backdrop, the FDA's present position that it need not comply in any respect with Defendant's requests for obviously critical discovery, is simply wrong.

First, you argue that the FDA need not comply with Defendant's subpoenas because the FDA is supposedly not a "person" under the Federal Rules of Civil Procedure.[4] Although you cite several cases to purportedly support of your position, you neglect to cite the decision from the Court of Appeals for the District of Columbia Circuit that directly addressed the question of whether Rule 45 subpoenas seeking the production of documents applies to federal agencies. In Houston Bus. Journal, Inc. v. Office of the Comptroller, 86 F.3d 1208 (D.C. Cir. 1996), the Court held unequivocally that:

> A federal-court litigant . . . can seek to obtain the production of documents from a federal agency by means of a federal subpoena.

Id. at 1212. The Court further held that to the extent a federal agency's regulation --

> may be to the contrary, it conflicts with Federal Rule of Civil Procedure 45 and exceeds the [agency's] authority under the Housekeeping Statute.

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[4] Rule 45 provides, in relevant part, that: "Every subpoena shall . . . command each person to whom it is directed to attend and give testimony or to produce and permit inspection and copying of designated books, documents or tangible things in the possession, custody or control of that person, or to permit inspection of premises, at a time and place therein specified." Fed. R. Civ. P. 45(1)(C).

Id. (emphasis added). None of the authorities upon which you rely challenge the validity and force of Houston Bus. Journal. In fact, a recent district court decision reaffirmed its precedential value. See Ho v. United States, 374 F. Supp. 2d 82 (D.D.C. 2005). Moreover, in this case, the federal government has affirmatively invoked the Federal Rules; and those Rules now govern discovery on the government in this matter. None of the authorities upon which you rely involved the federal government as the plaintiff in the lawsuit.[5] Houston Bus. Journal is good law and, as an agency of the federal government, you are bound to follow it with respect to Defendant's subpoena for documents.

Second, with respect to Defendant's subpoena for testimonial evidence, you argue that the FDA need not provide testimony because the subpoenas "do[] not comply with the criteria set forth in FDA's regulations, 21 C.F.R. part 20." Putting aside the fact that the FDA appears to have ignored or waived this supposed requirement when it came to providing informal testimony to the SEC in this matter, the subpoenas at issue are not directed to fact witnesses, but to FDA keepers of records. Pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure:

> A party may in the party's notice and in a subpoena name as the deponent a public or private corporation or a partnership or association or governmental agency and describe with reasonable particularity the matters on which examination is requested. In that event, the organization so named shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. A subpoena shall advise a non-party organization of its duty to make such a designation. The persons so designated shall testify as to matters known or reasonably available to the organization. This subdivision (b)(6) does not preclude taking a deposition by any other procedure authorized in these rules.

Fed. R. Civ. P. 30(b)(6) (emphasis added). This Rule by its very terms authorizes Defendant's keepers of records subpoenas on the FDA. Further, by statute, any conflict

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5 There is absolutely nothing in the language of the Federal Rules, or in the case law, to suggest that the application of the Federal Rules should be determined selectively on an agency-by-agency basis. Indeed, as you recognize in your letter, the question is whether the Rules apply to the "government." In this case, they most certainly do.

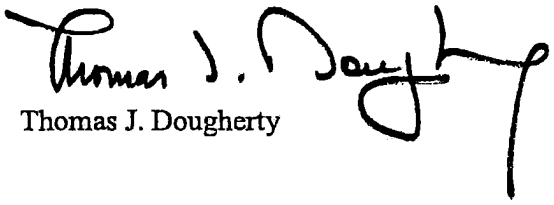
that this language has with other laws (including FDA regulations) is resolved in favor of the Rules. 28 U.S.C. § 2072 ("The Supreme Court shall have the power to prescribe general rules of practice and procedure and rules of evidence for cases in the United States district courts . . . All laws in conflict with such rules shall be of no further force or effect after such rules have taken effect.").

Third, you raise several privilege and burdensomeness objections. Assuming you are willing to comply with the subpoenas, we would be happy to discuss your objections with you request-by-request, at your earliest convenience. Please note, however, that we are defending a lawsuit in federal court that will be going to trial in the coming years for which the subpoena to the FDA provides foundational discovery for the rest of the discovery in the matter.

Fourth, to the extent the FDA has concern to protect the confidentiality of scientific or commercial information, we are prepared to discuss an appropriate protective stipulation and order.

I look forward to hearing from you.

Very truly yours,



Thomas J. Dougherty

Enclosures

EXHIBIT L

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SECURITIES EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No.: 05mc476 (RMU)
v.	:	
RICHARD SELDEN,	:	
Defendant.	:	

ORDER

HOLDING CASE IN ABEYANCE PENDING D.C. CIRCUIT RULING

On February 27, 2006, the Court of Appeals for the District of Columbia Circuit will hear the appeal of the district court's ruling in *Yousuf v. Samantar*, 2005 WL 1523385 (D.D.C. May 03, 2005). That appeal raises questions central to the issues presented before this court in the instant case. The court rules that it is in the best interests of justice to hold this case in abeyance pending a ruling by the D.C. Circuit in *Yousuf*. It is therefore this 10th day of February 2006 hereby

ORDERED that this case be held in abeyance pending a ruling by the D.C. Circuit in *Yousuf*, and it is

FURTHER ORDERED that the parties file supplemental memoranda to the court within 15 days of the D.C. Circuit's ruling and address the applicability of the holding in that case to the case at bar.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

EXHIBIT M

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
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March 29, 2006

BY OVERNIGHT COURIER

Dr. Andrew C. von Eschenbach
Acting Commissioner
U.S. Food and Drug Administration
Office of the Commissioner
Parklawn Building
Mail Code: HF-1
5600 Fishers Lane
Rockville, MD 20856

Re: S.E.C. v. Richard F. Selden
Civil Action No. 05-11805-NMG (D. Mass.)

To The Commissioner:

We refer you to the Food and Drug Administration's ("FDA's") failure to make the requisite replies to the following Touhy requests:

Oct. 28, 2005 Subpoena on FDA Keeper of Records ("Touhy 1") (Tab 1)
Oct. 28, 2005 Subpoena on CBER Keeper of Records ("Touhy 2") (Tab 2)*

This request constitutes yet another attempt to obtain information from the FDA on the issues herein identified. On behalf of Richard F. Selden ("Dr. Selden"), we hereby request, pursuant to 21 C.F.R. § 20.1(c), the sworn oral testimony of the

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* The FDA opposes compliance with Touhy 1 and Touhy 2, arguing that Rule 45 of the Federal Rules of Civil Procedure does not apply to the federal government, which position is presently the subject of motion to compel proceedings before the D.C. District Court. See S.E.C. v. Richard F. Selden, No. 1:05-ms-00476-RMU (D.D.C., filed Nov. 23, 2005). Regardless of the enforceability of the subpoenas as subpoenas, however, the FDA is required by its own regulations to treat the subpoenas as "Touhy" requests to the extent they call for the production of documents. 21 C.F.R. § 20.2(a).

following FDA staff members at a mutually convenient time and at the location indicated below:

Name	Location
James Kaiser	Skadden, Arps, Slate,
Dwaine Rieves	Meagher & Flom LLP
Marc K. Walton	1440 New York Avenue, N.W.
Karen Weiss	Washington, D.C. 20005-2111

The subject matter of the testimony sought by Dr. Selden concerns the allegations in a federal complaint filed on September 1, 2005, by the U.S. Securities and Exchange Commission ("SEC") against Dr. Selden in the U.S. District Court for the District of Massachusetts, a copy of which is attached at Tab 3. The testimony shall be used as part of the defense in that action.**

In addition, in advance of the testimony, we require the production of the documents identified in the respective Schedule As of Touhy 1 and Touhy 2. As always, we remain willing to negotiate the scope of the requests, on a request-by-request basis, to try to minimize the FDA's concerns about burden and to obtain promptly those documents that are essential to Dr. Selden's defense.

The foregoing requests are made by Dr. Selden with full reservation of all of his rights relating to the subpoenas. Dr. Selden believes he is entitled to full FDA compliance with the subpoenas, particularly in the context of this case, in which the government is the plaintiff and the FDA actively cooperated with and supported the SEC in bringing the action.

** The SEC took the ex parte, sworn testimony from Marc K. Walton pursuant to requests made on or about June 25, 2003. See the June 26, 2003 letter from Lana L. Ogram, Director, Division of Compliance Policy to David P. Bergers, SEC Assistant District Administrator (referencing June 25, 2003 request), attached at Tab 4.

Please let me know if you have any questions.

Sincerely yours,

Justin J. Daniels

I verify under penalty of perjury that the foregoing is true and correct. Executed on March 29, 2006.

Justin J. Daniels

Attachments

EXHIBIT N

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
RETURN RECEIPT

June 30, 2006

Justine J. Daniels, Esquire
Skadden, Arps, Slate, Meagher & Flom LLP
One Beacon Street
Boston, Massachusetts 02108-3194

Dear Mr. Daniels:

This is in response to your letter dated March 29, 2006, requesting testimony from the Food and Drug Administration (FDA). Your letter specifically requested authorization for the testimony of Mr. James Kaiser, Mr. Rafel "Dwaine" Rieves, Dr. Marc K. Walton and Ms. Karen Weiss in connection with a case entitled SEC v. Selden, Civ. No. 05-11805 (D. Mass. filed Sept. 1, 2005).

As you know, your request for the testimony of an FDA employee is governed by the U.S. Code of Federal Regulations (C.F.R.), Title 21 Part 20. This regulation prohibits any FDA employee from providing testimony before any tribunal pertaining to any information acquired in the discharge of his or her official duties except with the express authorization of the Commissioner of Food and Drugs or an employee designated by him to act on his behalf. As Director of the Division of Compliance Policy in the Office of Enforcement, I have been delegated the authority by the Commissioner of Food and Drugs to review any requests made under 21 C.F.R. Part 20.

Congress has charged FDA with the authority to enforce the Federal Food, Drug, and Cosmetic Act (FDCA) and other laws aimed at protecting the nation's health. In fulfilling this vital function, FDA regulates the manufacture, import, storage, promotion, sale, and distribution of nearly one trillion dollars worth of foods, drugs, devices, biological products, and cosmetics produced annually by more than 100,000 businesses worldwide. FDA has limited resources and must continuously make difficult policy decisions as to how it may best allocate its restricted staff and finite budget. Were FDA to provide testimony in all cases involving products regulated by the agency, key agency personnel would spend an inordinate amount of time preparing for and providing testimony in litigation to which the agency is not a party. This would substantially inhibit FDA's ability to effectively safeguard the public health.

Section 20.1, 21 C.F.R., provides that a request for testimony may be granted upon a determination that the testimony requested both is in the interest of the public health and in furtherance of the objectives of the FDCA and the agency. Because of FDA's limited resources and the vast number of requests the agency receives for its personnel to testify in litigation to which FDA is not a party, FDA may, in its discretion, disapprove a request for testimony even when these prerequisites have been met. In addition, FDA must deny requests that are duplicative, unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate. The agency must therefore carefully assess requests for testimony made pursuant to section 20.1.

After considering the merits of your requests, FDA has determined that your request to depose Dr. Marc K. Walton is in the public interest and promotes the objectives of the FDCA and the agency, and hereby authorizes him to provide certain testimony. Dr. Walton's deposition testimony shall take place at one time only, at an agreed-upon location, and shall not exceed seven (7) total hours. The deposition may be videotaped so that it may be used at trial in lieu of Dr. Walton's appearance. No information entitled to protection as a trade secret shall be revealed by Dr. Walton. See 21 U.S.C. § 331(j). Dr. Walton will testify only to facts regarding FDA's drug approval process and his involvement in that process as it relates to Trankaryotic Therapies Inc.'s Replagal product. He will not offer expert opinions on any manner and will be instructed not to answer any questions outside of the scope of the questioning authorized by this letter. You may contact Jennifer Zachary, Esq., in FDA's Office of Chief Counsel at 301-827-9572 to arrange a time and date for Dr. Walton's testimony.

In addition, pursuant to 21 C.F.R. § 20.1, I am denying your request for the testimony of Mr. James Kaiser, Mr. Rafel Rieves, and Ms. Karen Weiss because their testimony will likely be duplicative of Dr. Walton's testimony. If you have any further questions about this letter, please contact Ms. Anne Smith at 240-632-6844.

Sincerely yours,

for Carl E. Draper

Lana L. Ogram
Director
Division of Compliance Policy
Office of Enforcement

EXHIBIT O

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

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July 12, 2006

BY OVERNIGHT U.S. MAIL

Lana L. Ogram
Director, Division of Compliance Policy
c/o Anne P. Smith (HCF-230)
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: SEC v. Richard F. Selden
Civil Action No. 05-11805-NMG (D. Mass.)

Dear Ms. Ogram:

I am writing in response to your letter of June 30, 2006, which we received on July 10, 2006, regarding our requests for testimony from James Kaiser, Dwaine Rieves, Marc Walton and Karen Weiss, which we made on behalf of Dr. Richard Selden in connection with the above-captioned litigation. Respectfully, we believe that your decision not to authorize any testimony from either Kaiser, Rieves or Weiss, on the grounds that the testimony would be "duplicative," is both improper under the circumstances and factually incorrect. Similarly, we believe it is inappropriate under the circumstances to limit Dr. Walton's testimony to "facts regarding FDA's drug approval process and his involvement in that process as it relates to Transkaryotic Therapies, Inc.'s Replagal product." We respectfully request that you reconsider your position and permit the testimony as requested.

A. The Special Circumstances Of This Case

Unlike the typical Touhy request for testimony, in this case Dr. Selden is a defendant in a civil enforcement action brought by the United States government. His requests are made solely in connection with his defense in that action. The SEC has charged Dr. Selden with securities fraud relating to the public disclosures by Transkaryotic Therapies, Inc. ("TKT"), of which Dr. Selden was formerly the CEO, concerning the regulatory status of TKT's biologics license application ("BLA") for

Replagal and the relation of that status to the BLA for a similar product submitted concurrently by Genzyme Corporation. The FDA plays a critical role in Dr. Selden's defense of the SEC action. Further, the SEC has had the assistance and cooperation of the FDA. For example, the FDA has already permitted the SEC to conduct informal "off the record" interviews of Dr. Walton. Permitting private citizens a complete defense to a federal governmental enforcement action is surely in the public interest.

B. The Different Roles Of Drs. Weiss, Walton, Rieves and Kaiser

In addition to the special circumstances articulated above, it is incorrect that the other witnesses' testimony will be duplicative of Dr. Walton's testimony. Although the other witnesses, like Dr. Walton, were all involved with the review of TKT's BLA for Replagal in one way or another, that is where the similarity ends. Each of these individuals in fact played unique and distinct roles in the process, were of different levels of seniority, had different interactions with the company, and spent varying amounts of time on the BLA.

Dr. Weiss. Dr. Weiss was Dr. Walton's supervisor in connection with the clinical review of TKT's BLA for Replagal. She was at a decision-making level in regard to the application. She also had conversations with TKT representatives that were not attended by Dr. Walton or the other witnesses. Only she can competently testify as to those conversations and to her knowledge regarding the decision-making process at FDA concerning the BLA. Even Dr. Rieves indicated in written documentation that Dr. Weiss, not Dr. Walton, would be involved in deciding what statistical measures and weightings to apply in gauging the efficacy of the Replagal product. Dr. Weiss was also the signatory on certain important correspondence from the FDA to TKT and thus has personal knowledge of that correspondence.

Dr. Rieves. Dr. Rieves was the primary reviewer for the BLA for Replagal. He had extensive conversations with TKT representatives outside the presence of Dr. Walton or the other requested witnesses. Unlike Dr. Walton, we believe, Dr. Rieves personally reviewed the raw data provided by TKT during the course of the BLA process. It is also our understanding that Dr. Rieves was responsible for the first draft both of the "complete response letter" provided to TKT on January 3, 2001 as well as the FDA's August 2002 "briefing book" prepared for the FDA Advisory Committee Meeting.

Dr. Kaiser. It is our understanding that Dr. Kaiser, unlike the other witnesses, had a more direct role in connection with the design of TKT's clinical trials for Replagal as part of the IND. He also had extensive conversations with TKT outside the presence of the other witnesses.

Dr. Walton. While Dr. Walton certainly played a part in the FDA's review of TKT's BLA for Replagal, he was far from the only individual involved. In fact, he testified to the SEC on July 22, 2003 that he spent only 10% of his time on the BLA. Further, he was not the primary reviewer of the BLA.

Finally, for the reasons stated above, even if there is subject matter for which these witnesses share knowledge, that is not grounds to preclude their testimony where the individual requesting the testimony is a defendant in a federal court action brought by the federal government with the active assistance and cooperation of the FDA.

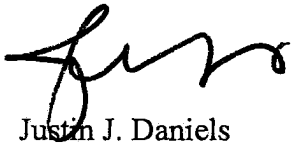
C. Restricting Dr. Walton's Testimony Is Inappropriate Under The Circumstances

You do not explain why you have determined to limit the scope of permissible questions of Dr. Walton, although we presume from the context of the letter that the reason has to do with issues of confidentiality. Again, we want to emphasize that these requests are being made in the context of a civil litigation instituted by the United States government against Dr. Selden in federal court. The FDA's objections to Dr. Walton's testimony on the grounds of confidentiality are therefore unfounded because it is common in such situations for the parties to stipulate to, and for the Court to order, the protection from disclosure of confidential information produced in the action. We would be happy to discuss the appropriate language for such a stipulation.

We ask that you please reconsider the FDA's position. We are available to discuss any of this at your convenience.

Please let me know if you have any questions.

Sincerely yours,



Justin J. Daniels

cc: Jennifer Zachary, Esq. (FDA Office of Chief Counsel)

EXHIBIT P

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

ORDER

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

For the reasons stated in the Memorandum Opinion contemporaneously filed herewith, it is this 16th day of August, 2006,

ORDERED that defendant Selden's motion to compel is **GRANTED**, and it is

FURTHER ORDERED that the FDA's motion to quash is **DENIED**, and it is

ORDERED that the FDA comply with Selden's subpoenas in accordance with the FDA's *Touhy* regulations, and it is

FURTHER ORDERED that the parties provide this court (and a courtesy copy to the trial court in Massachusetts) with a joint status report outlining the parties' anticipated timing for

the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations.

The parties must file their joint status report within 7 days of this order.

SO ORDERED.

RICARDO M. URBINA
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: SUBPOENAS IN SECURITIES AND EXCHANGE COMMISSION,	:		
Plaintiff,	:	Misc. No.:	05-0476 (RMU)
v.	:	Document No.:	1, 7
RICHARD F. SELDEN,	:		
Defendant,	:		
and,	:		
FOOD AND DRUG ADMINISTRATION,	:		
Interested Party.	:		

MEMORANDUM OPINION

GRANTING DEFENDANT SELDEN'S MOTION TO COMPEL;
DENYING THE FDA'S MOTION TO QUASH

I. INTRODUCTION

The United States Securities and Exchange Commission ("SEC") filed a securities enforcement action against Richard F. Selden in federal court in Massachusetts. In preparing his defense, Selden served two subpoenas on the United States Food and Drug Administration and the Center for Biologics Evaluation and Review, a division of the Food and Drug Administration (collectively, the "FDA").

In the instant action, Selden seeks to compel the subpoenas *duces tecum* he served on the FDA. The FDA seeks to quash the subpoenas arguing that Selden failed to comply with the FDA's regulations governing requests for document production and that the subpoenas are

unduly burdensome. Because the FDA's regulations require it to treat subpoenas as requests for records, and because the FDA has not yet processed Selden's subpoenas in accordance with those regulations, the court compels the FDA's compliance with the subpoenas and denies the FDA's motion to quash. Because the FDA has not yet processed Selden's subpoenas, the court cannot assess whether any document production would be unduly burdensome.

II. BACKGROUND

A. Factual Background

On September 1, 2005, the SEC filed a securities enforcement action against Richard F. Selden in the United States District Court for the District of Massachusetts. *SEC v. Selden*, Civ. No. 05-11805 (D. Mass. Sept. 1, 2005); Mot. to Compel at 1. The SEC's complaint alleges that Selden, in his position as chief operating officer for Transkaryotic Therapies, Inc. ("TKT"), a small biotechnologies firm, interfered with the FDA's review of TKT's drug, Replagal, for domestic marketing approval.[1] Mot. to Compel at 1. Specifically, the SEC alleges that Selden made "materially misleading public statements by TKT about the status of the FDA application for Replagal." Mot. to Compel, Ex. C ¶ 1.

To prepare his defense, Selden served two subpoenas on the FDA for testimony and

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[1] Replagal is a TKT drug used for the treatment of Fabry disease, a rare genetic disorder caused by a missing enzyme needed to metabolize lipids in the body. Mot. to Compel at 1.

documents relating to Replagal, TKT, and Selden, or otherwise relating to the underlying case.[2] Mot. to Compel at 2; Mot. to Compel Ex. A-B; Mot. to Quash at 2-3. In a letter dated November 9, 2005, the FDA objected to the subpoenas and requested that Selden withdraw them.[3] Mot. to Compel Ex. D ("Objection Letter"). In numerous letter between the FDA and Selden, the FDA reiterated its objections to the subpoenas and encouraged Selden to file his request for documents pursuant to the Freedom of Information Act ("FOIA"). Mot. to Quash at 5-6. Selden did not withdraw the subpoenas but instead reasserted his need for the information in preparing his defense in the securities enforcement action in Massachusetts. Mot. to Compel at 2.

2. Procedural Background

On February 10, 2006, this court held the case in abeyance pending a ruling by the United States Court of Appeals for the District of Columbia in the case of *Yousuf v. Samantar*, 451 F.3d 248 (D.C. Cir. 2006). Order (Feb. 10, 2006). On June 16, 2006, the Court of Appeals issued its ruling and held that a government agency is a "person" under Rule 45 and, therefore, can be the target of a third-party subpoena. *Yousuf*, 451 F.3d 248. Following the Court of

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[2] The subpoenas for testimony are not at issue here. The FDA responded to Selden's request for testimony by allowing the deposition of Dr. Marc K. Walton and denying Selden's request for testimony from James Kaiser, Rafel Rieves, and Karen Weiss. Supplemental Mem. in Supp. of Mot. to Quash Ex. 2. Selden has not objected to the FDA's denial of his request for testimony.

[3] The FDA objects to the subpoenas on the grounds that (1) the FDA is not a "person" within the meaning of Rule 45 and therefore cannot be the subject of a third-party subpoena; (2) the subpoenas do not comply with the FDA's *Touhy* regulations; (3) the requested documents contain "trade secrets and confidential commercial information;" (4) the requested documents are "exempt from public disclosure by the deliberative process privilege and personal privacy regulations;" (5) the subpoenas do not give the FDA "a reasonable time to respond;" and (6) the subpoenas are "unduly burdensome and over broad because they [seek] documents that [are] more than 18 years old, and because they [seek] certain documents that are publicly available in electronic format on the internet." Mot. to Quash at 4-5; Mot. to Compel Ex. D ("Objection Letter").

Appeals' decision, the parties submitted supplemental memoranda to the court addressing the applicability of *Yousuf* to the present case. Supplemental Mem. in Supp. of Mot. to Compel ("Supp. Mem. to Compel"); Supp. Mem. in Support of Mot. to Quash ("Supp. Mem. to Quash").

In his supplemental memorandum, Selden again seeks the FDA's compliance with the subpoenas and asks the court to compel full disclosure by August 31, 2006, so that Selden can prepare his defense in the Massachusetts action.[4] *Id.* The FDA continues to object to the subpoenas on the grounds that (1) the subpoenas do not comply with the FDA's *Touhy* regulations governing information requests, and that (2) the FDA would be unduly burdened by compliance with the subpoenas.[5] Supp. Mem. to Quash, 6-11. The FDA, therefore, asks the court to quash the subpoenas or, in the alternative, to (1) narrow the scope of the subpoenas; (2) provide a "reasonable time period" for the FDA to respond; and/or (3) require Selden pay the costs of the requested production. *Id.* at 12-14. The court now turns to these claims.

III. ANALYSIS

1. Legal Standard for *Touhy* Regulations

A federal government agency may create procedures for responding to subpoenas and requests for testimony pursuant to 5 U.S.C. § 301, the federal "housekeeping" statute. *Bobreski v. EPA*, 284 F. Supp. 2d 67, 73 (D.D.C. 2003); *see also United States ex rel. Touhy v. Ragen*, 340

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[4] According to Selden, the parties in the Massachusetts action must complete all written discovery by October 30, 2006. Supp. Mem. to Compel, 8.

[5] Following the Court of Appeals' decision in *Yousuf*, the FDA has abandoned its claim that the government is not a "person" within the meaning of Rule 45. *See* Supp. Mot. to Quash, 1-2.

U.S. 462, 468 (1951). Specifically, § 301 authorizes the head of an agency to "prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use and preservation of its records, papers and property." *Bobreski*, 284 F. Supp. 2d at 73 (quoting 5 U.S.C. § 301). These regulations, generally called *Touhy* regulations, serve the government's need to make a "centraliz[ed] determination as to whether subpoenas duces tecum will be willingly obeyed or challenged[.]" *Touhy*, 340 U.S. at 468.

B. The Court Grants Selden's Motion to Compel and Denies the FDA's Motion to Quash the Subpoenas

The FDA maintains that Selden's subpoenas did not constitute valid requests for documents under the FDA's *Touhy* regulations. Mot. to Quash at 17-21; Supp. Mot. to Quash at 6-9. The FDA claims, therefore, that it is not required to respond to the subpoenas. *Id.*

Federal agencies must "follow their own rules, even gratuitous procedural rules that limit otherwise discretionary actions." *Steenholdt v. FAA*, 314 F.3d 633, 639 (D.C. Cir. 2003) (citing *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)). Under the FDA's own rules, "[a]ny request for records of the Food and Drug Administration, whether it be by letter *or by a subpoena duces tecum* or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part[.]" 21 C.F.R. § 20.2(a) (emphasis added). Under Subpart B, the FDA handles subpoenas *duces tecum* in accordance with the procedures for the production of all agency records pursuant to FOIA. 21 C.F.R. § 20.2(b).

Holding the FDA to its own rules then, the FDA must treat the subpoenas as requests for documents pursuant to its *Touhy* regulations and respond in kind. *Id.*; *see also* Supp. Mem. to

Quash Ex. 3 (Apr. 6, 2006 Selden Letter) (identifying the FDA's own regulations as requiring subpoenas to be treated as *Touhy* requests). And because the FDA must treat the subpoenas *duces tecum* as requests for documents under its *Touhy* regulations, the FDA must respond to Selden's subpoenas pursuant to its *Touhy* regulations.[6] Accordingly, the court grants Selden's motion to compel and denies the FDA's motion to quash the subpoenas.

C. The Court Declines to Rule on Whether the Subpoenas are Unduly Burdensome

The FDA must submit the subpoenas to its *Touhy* process pursuant to the court's ruling. The FDA argues, however, that compliance with the subpoenas would be unduly burdensome. But, because the agency has not yet taken the appropriate administrative action on these requests under its regulations, the extent of any document production pursuant to Selden's request is, at this juncture, speculative. The court, therefore, is unable to assess the FDA's argument that compliance would be burdensome. Accordingly, the court declines to rule on the FDA's objection that the subpoenas are unduly burdensome, declines to rule on the FDA's motion to modify the subpoenas, and orders the FDA to proceed under the policies it has set forth in its

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[6] Relying on the Court of Appeals' decision in *Yousuf*, Selden contends that he is entitled to immediate access to the documents; that he need not wait on the FDA's *Touhy* process. Supp. Mem. to Compel at 6-7. In *Yousuf*, the D.C. Circuit held that a government agency could be the subject of a third-party subpoena under Rule 45 of the Federal Rules of Civil Procedure. 451 F.3d at 250. Selden reads this decision as allowing a litigant, in subpoenaing a government agency, to bypass that agency's *Touhy* process altogether. Supp. Mem. to Compel at 6-7. Selden misapprehends the Court of Appeals' decision. In *Yousuf*, the court did not suggest that a litigant would be able to bypass a federal agency's *Touhy* regulations by subpoenaing the agency. In fact, the court explicitly acknowledged the role of *Touhy* regulations as the vehicle through which a federal agency responds to a subpoena *duces tecum*. *Yousuf*, 451 F.3d at 257 (citing *Touhy*, 340 U.S. at 464, 469). Accordingly, Selden must wait for the FDA to process his subpoenas under its *Touhy* regulations.

Touhy regulations.[7]

IV. CONCLUSION

For the foregoing reasons the court, this 16th day of August, 2006, compels the FDA's compliance with Selden's subpoenas in accordance with the FDA's *Touhy* regulations. An order instructing the parties in a manner consistent with this Memorandum Opinion is issued contemporaneously.

RICARDO M. URBINA
United States District Judge

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[7] The court notes that the FDA must proceed through its *Touhy* process prior to any document production and that, under its procedures, it will treat the subpoenas as FOIA requests. 21 C.F.R. § 20. The FDA indicates that the parties have made "significant progress" in negotiating the scope of Selden's document requests and that Selden has already received approximately 300 pages of responsive documents from the FDA. Supp. Mem. to Quash at 4-5. Selden contends that, although engaging in dialogue, the FDA has not produced any documents in response to his subpoenas. Supp. Mem. to Compel, 8.

Though delay will not affect this court's docket, the court reminds the FDA that Selden wants these documents to prepare a defense to the pending action in the United States District Court for the District of Massachusetts. Thus, the FDA must engage Selden's request, and formulate a response, with dispatch (rather than place Selden's subpoena request at the back of the FOIA que). Toward that end, the court orders the parties to provide this court and the trial court in Massachusetts with a joint status report outlining the parties' anticipated timing for the FDA's fulfillment of Selden's subpoena requests pursuant to the FDA's *Touhy* regulations. The court anticipates and expects the FDA's good faith, prompt, and satisfactory compliance in this endeavor.

EXHIBIT Q

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENAS IN:

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Miscellaneous Case No. 05-0476 (RMU)
v.	:	(Related Case: Civ. No. 05-11805-NMG Pending in the United States District Court for the District of Massachusetts)
RICHARD F. SELDEN,	:	
Defendant,	:	
and,	:	
FOOD AND DRUG ADMINISTRATION,	:	
Interested Party.	:	

JOINT STATUS REPORT REGARDING FDA COMPLIANCE WITH DEFENDANT RICHARD F. SELDEN'S FEDERAL SUBPOENAS

Pursuant to this Court's August 16, 2006 Order granting defendant Richard F. Selden's ("Dr. Selden's") motion to compel the United States Food and Drug Administration's ("FDA's") compliance with two federal subpoenas issued by Dr. Selden out of this Court on October 28, 2005, Dr. Selden and the FDA (collectively, the "Parties") respectfully submit this joint status report regarding the scope and expected timing for FDA compliance.

Exhibit A, attached hereto, provides the current status of FDA compliance with each of the thirteen requests for documents contained in Dr. Selden's "Schedule A" to the subpoenas, along with FDA's proposed timing for completed production.

Exhibit B, attached hereto, identifies five open issues, along with a summary of the Parties' respective positions. Dr. Selden respectfully requests a conference before the Court to address these issues.

Respectfully submitted,

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(301) 827-0238

Counsel for Interested Party
Food and Drug Administration

August 25, 2006

CERTIFICATE OF SERVICE

I, _____, hereby certify that on August 25, 2006, I caused a true copy of the foregoing Joint Status Report Regarding FDA Compliance With Defendant Richard F. Selden's Federal Subpoenas to be served by U.S. mail upon:

Frank Huntington
United States Securities and Exchange Commission
Boston District Office
33 Arch Street, 23rd Floor
Boston, Massachusetts 02110

Dated: August 25, 2006

_____

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
1. All FDA documents relating to FDA's consideration of surrogate endpoints for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, including, but not limited to, all: A) internal FDA correspondence and documents relating to Dr. Selden, TKT, Replagal, the Fabrazyme Biologic License Application ("BLA"), or any Fabrazyme-related Investigational New Drug Application ("IND"); and B) materials from the Jan. 2003 FDA advisory committee meeting relating to Replagal or Fabrazyme. FDA will not produce: - documents submitted by TKT - Fabrazyme documents relating exclusively to chemistry, manufacturing, or controls ("CMC") - Fabrazyme documents generated after 4/23/03	A) FDA has an estimated 15,375 pages of potentially responsive documents, requiring 768 hours of review time. Anticipated production date uncertain.[2] B) FDA has an estimated 3,500 pages of potentially responsive documents, requiring 175 hours of review time. Anticipated production date uncertain.
2. All FDA documents relating to FDA's consideration of dual approval for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 4, 6, and 7.	See timing for Schedule A request 1.
3. Every complete response letter ("CRL") issued by the FDA's Center For Biologics Evaluation And Review ("CBER") from 1987 to the present.	**Open Issue, see Ex. B infra.**	If this request is narrowed to include every CRL issued by CBER in 2000 and 2001, subject to the criteria listed below in Exhibit B, FDA has identified 30 CRLs responsive to this request, totaling an estimated 393 pages and requiring 20 hours of review time. Anticipated production date of 10/3/06.
4. All documents relating to Replagal.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 6, and 7.	See timing for Schedule A request 1.
5. All documents relating to TKT but not to Replagal.	No production necessary.	N/A

Exhibit A

Schedule A Request (paraphrased)	Negotiated FDA Production	FDA's Proposed Timing[1]
6. All documents relating to Dr. Selden.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 4, and 7.	See timing for Schedule A request 1.
7. All documents relating to Fabrazyme through 4/24/03.	FDA will produce all: A) CRLs sent to Genzyme regarding Fabrazyme; B) Genzyme responses to Fabrazyme CRLs, except portions relating exclusively to CMC; C) correspondence between Genzyme and FDA, in addition to CRLs and CRL responses, relating to Fabrazyme; D) portions of the original Fabrazyme BLA or any Fabrazyme-related IND relating to clinical, safety, efficacy and/or clinical trials; E) internal FDA correspondence and documents relating to the Fabrazyme BLA or any Fabrazyme-related IND, except documents generated after 4/23/03; and F) materials from the Jan. 2003 FDA advisory committee meeting relating to Fabrazyme, except the meeting transcript and materials submitted by TKT.	A) FDA has already identified an estimated 25 pages of responsive documents, requiring 1.25 hours of review time. Anticipated production date of 9/29/06. B) FDA has an estimated 75 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 7,500 to 37,500 pages) of potentially responsive documents, requiring between 375 and 1,875 hours of review time. Anticipated production date uncertain. C) Anticipated production date of 12/31/06. D) FDA has an estimated 46 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 4,600 to 23,000 pages) of potentially responsive documents, requiring between 230 and 1,150 hours of review time. This estimate does not include any documents from any Fabrazyme-related INDs, which may contain even more potentially responsive documents. Anticipated production date uncertain. E) See timing for Schedule A request 1. F) See timing for Schedule A request 1.
8. All documents relating to the SEC lawsuit or any other actual/possible lawsuit involving TKT or Replagal.	FDA will produce all responsive documents, except: - documents submitted by TKT - documents unrelated to Replagal	FDA has an estimated 500 pages of potentially responsive documents. Anticipated production date of 12/31/06.

Exhibit A

Schedule A Request (paraphrased)	Negotiated FDA Production	FDA's Proposed Timing[1]
9. All guidelines for CBER review of BLAs, INDs, trials, protocols, etc.	FDA will produce any internal FDA manuals, guidelines or templates available for reference or use, as of January 1, 1996 or later, in connection with the review of a BLA or IND.	FDA has an estimated 41,000 pages of responsive documents, requiring 2050 hours of review time. Anticipated production date uncertain.
10. Record retention schedules under 21 C.F.R. § 20.23(c)	FDA will produce its Headquarters Record Control Schedule, last updated on 12/31/89, which FDA represents was the applicable record retention schedule for the period 1990 to present.	FDA has already collected 104 pages of responsive documents. Anticipated production date of 9/1/06.
11. All documents relating to the dissolution/potential dissolution of CBER.	No production necessary.	N/A
12. Any proposed or final documents relating to guiding public disclosure of BLA status.	FDA will produce any internal FDA proposals or draft guidelines relating to the public disclosure, by the applicant, of the status of the applicant's BLA.	FDA's preliminary search has not identified any documents responsive to this request.
13. All documents relating to joint FDA/SEC coordination.	FDA will produce all correspondence and communications, and all documents reflecting, memorializing or referring to any correspondence or communications, between FDA and the SEC relating to Dr. Selden, TKT, Replagal, or any joint FDA/SEC efforts to enhance inter-agency cooperation.	In addition to those documents identified as responsive to Schedule A Request 8, FDA has an estimated additional 1000 pages of potentially responsive documents. Anticipated production date of 12/31/06.

[1] Productions will be made by four different components within FDA on a rolling basis, and the anticipated production date is the final date by which the production of this category of documents will be completed by all FDA components. Estimates of the number of FDA staff hours necessary for production are based on an estimated 3 minutes per page for review and redaction of documents. FDA will provide a privilege log no later than 90 days after the completion of the production of each category of documents described above.

[2] See Exhibit B, Open Issue 1.

Exhibit B

Issue #1: Timing of FDA production of documents

FDA's position:

FDA is unable to provide the Court with an exact date for its completion of production of all documents responsive to Subpoena Requests 1, 2, 4, 6, 7(B), (D)-(F), and 13 because FDA's initial search has identified an estimated 120,375 pages of documents that are potentially responsive to these requests. Presently, FDA estimates that it will take two months to collect and organize these documents and twenty months to complete the review, redaction, and supervisory review of the redactions (assuming three full-time employees are assigned to work on this project for six to eight hours per day, and spend approximately 3 minutes per page for review and redaction). Thus, based on an estimated volume of up to 120,375 pages of documents, the total time to production is expected to be twenty-two months from the day the search begins. FDA will make every effort to adhere to this timeframe. If less than 120,375 pages of documents are ultimately identified, or if Dr. Selden is able to further refine his request as outlined below, the review and redaction times can be reduced proportionately (e.g., if only 71,975 pages are identified, the time to production could be reduced to about thirteen months). If more than 120,375 pages are ultimately identified, the review and redaction times would be increased (e.g., if 140,000 pages are identified, the time to production would increase to twenty-seven months).

With respect to Subpoena Request 7(B), FDA has immediately available the three CRLs that FDA sent to Genzyme relating to its Fabrazyme product, as well as the table of contents for Genzyme's responses to these three CRLs. With respect to Subpoena Request 7(D), FDA has immediately available the table of contents for the portions of the original BLA for Fabrazyme that relate to clinical safety and efficacy, as well as a Genzyme-prepared overview of the clinical safety and efficacy portion of the original BLA for Fabrazyme. In the interest of prioritizing the

Exhibit B

FDA resources that must be marshaled to produce documents pursuant to this request, FDA proposes to provide Dr. Selden with these tables of contents and overviews so that Dr. Selden can identify the order of priority for production of the documents that are responsive to this request. If Dr. Selden is willing to narrow his request using these materials, the time required by FDA for the production of the documents he seeks could be significantly reduced.

Dr. Selden's Position:

The Court in the District of Massachusetts has already extended the pre-trial calendar in SEC v. Selden by six months to accommodate FDA's delay in responding to the subpoenas. The current schedule now requires all written discovery to be completed by October 30, 2006, with all depositions to be completed by end of February 2007. Nevertheless, the FDA now says that it will need another 22 months -- or until the middle of 2008 -- to complete the production. Surely this could not be the "prompt" FDA response that the Court had in mind when granting Dr. Selden's motion to compel (see Memorandum Opinion, Docket Entry No. 19 at 7 n.7), given that it would render the subpoenas essentially meaningless. Further, it would deny Dr. Selden a fair defense against a government enforcement action brought with the assistance of FDA itself. Lastly, FDA's proposed 22-month schedule is not defensible because it does not jibe with the realities of litigation document review. For example, under FDA's estimate, it will take six weeks for one person to review and process a single box of documents.[3] Even a conservative estimate of the review time for a box of documents in a complex litigation would be no more than 4-5 days per box, a period that can be accelerated with additional resource commitment or,

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[3] This figure is derived as follows: The FDA estimates a total production of 120,375 pages of documents. One standard size file box (or "banker's box") can hold approximately 2,500-3,000 pages of documents. FDA says it will take three people 22 months to complete this production, meaning that one person will need 22 months to complete approximately 13-16 boxes, or 6-7 weeks per box, per person.

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specific to FDA, a waiver of the deliberative process privilege (see Issue #3, below). Thus, the Court should order FDA to comply with the subpoenas on an accelerated basis by October 30, 2006, the end of the written discovery period in SEC v. Selden.

Issue #2: Request No. 3[4]

(A) Time range for CRLs to be produced

FDA's position:

FDA has agreed to produce every CRL issued by CBER between January 1, 2000 and December 31, 2001, excluding those CRLs issued for products that were never approved, those CRLs sent in response to Biologic License Application ("BLA") supplements rather than original applications, and those CRLs issued for products for which user fees were not collected. Applying these criteria to narrow Dr. Selden's request ensures that only CRLs issued for products with applications that are similar to Replagal's application will be produced. The January 1, 2000 and December 31, 2001 time period proposed by FDA will result in the production of all such CRLs for the year proceeding and the year following FDA's issuance of the Replagal CRL, which was issued in January 2001.

FDA has identified 30 CRLs for products fitting the above criteria that were issued during the relevant two-year time period. This search required twelve hours of FDA staff time, the review and redaction of these CRLs will require an additional 20 hours, and production

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[4] Request No. 3 of Schedule A calls for "[e]very complete response letter ('CRL') issued by the FDA's Center For Biologics Evaluation And Review ('CBER') from 1987 to the present." The SEC v. Selden case concerns the Complete Response Letter of Transkaryotic Therapies, Inc. ("TKT"). In that action, the SEC alleges Dr. Selden fraudulently misrepresented what the CRL said and meant. Complete Response Letters (sometimes referred to as "Complete Review Letters" or "CRLs") are "issued [by CBER] when the complete review indicates that there are deficiencies remaining that preclude the approval of the application or supplement at that time. The Complete Response Letter will: Summarize all of the deficiencies remaining, and [w]here appropriate, describe actions necessary to place the application/supplement in a condition for approval." CBER Manual Of Standard Operating Procedures And Policies ("SOPP") 8405, version #4 (eff. Sept. 20, 2004). The definition of CRL has also been revised several times during the relevant period.

Exhibit B

should be complete by 10/3/06. If FDA were ordered to produce every CRL issued by CBER during the 18-year period sought by Dr. Selden, the resulting massive undertaking would require years of FDA staff time to search for, organize, review, redact, and produce the estimated 400,000 pages of responsive documents. As FDA has consistently maintained, such a request is "unduly burdensome and over broad" because it seeks documents "more than 18 years old," encompasses "many thousands of pages," and would thus "further strain FDA's already overburdened document production capacity." FDA Motion to Quash at 4, 8.

Dr. Selden's Position:

FDA's refusal to produce CRLs beyond the years 2000 and 2001 is a new position that FDA took only in the last three weeks. Nevertheless, Dr. Selden is willing to agree to a protocol that would make the production non-burdensome on FDA (see 2.B., below), but FDA has not been willing to discuss this option.

(B) Open issue regarding production of CRLs for unapproved products

FDA's position:

FDA may not produce any CRLs for products that have not been approved because its regulations forbid FDA from releasing any information regarding unapproved BLA's. See 21 C.F.R. § 601.51(b) ("The existence of a biological product file will not be disclosed by the Food and Drug Administration before a biologics license application has been approved unless it has previously been disclosed or acknowledged."). The very existence of a BLA for a product that has not yet received FDA approval may be considered trade secret and confidential commercial information ("CCI"), and FDA's release of such information could constitute a violation of both the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and the Federal Trade Secrets Act, 18 U.S.C. § 1905, both of which carry individual criminal liability. See Jerome Stevens Pharms.

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v. FDA, 319 F. Supp. 2d 45 (D.D.C. 2004), aff'd in part, rev'd in part, 420 F.3d 1249 (D.C. Cir. 2005) (seeking $1.345 billion in damages for FDA's alleged release of trade secret and CCI contained in a new drug application).

Neither of these statutes, nor FDA's regulations, provide for an "attorneys' eyes only" exception for the release of trade secret or CCI. Should the court order FDA to produce the CRLs that Dr. Selden seeks, FDA would need to alert the hundreds of entities to whom these unapproved CRLs were issued during this 18-year period to permit them to intervene in the present action to defend their proprietary information. See 21 C.F.R. § 20.48 (requiring FDA to give notice to "a person who will be affected by a proposed disclosure of data or information contained in Food and Drug records" to permit them "to institute suit in a United States District Court to enjoin release of the records" and prohibiting FDA from "disclos[ing] the records involved until the matter and all related appeals have been concluded").

Dr. Selden's Position:

FDA's stated position derives from a premise not at issue here; namely, that Dr. Selden is seeking the public disclosure of confidential information. Not so. Dr. Selden's interest in the materials is limited to defending himself in the government enforcement action; and FDA regulations specifically provide a process for limited disclosure of non-public information in connection with court proceedings:

> Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

Exhibit B

21 C.F.R. § 20.86 ("Disclosure in administrative or court proceedings") (emphasis added). Further, contrary to FDA's blanket assertion that it cannot produce any non-public information without an extensive notice period and the exhaustion of all legal remedies by those affected, FDA regulations contemplate production subject to measures that can be adopted "to reduce disclosure to the minimum necessary under the circumstances."

Consistent with the above, Dr. Selden is willing to agree to the entry of a protective order that would protect the confidentiality of the CRLs while permitting him limited use for purposes of his defense. However, to date FDA has refused to engage in any dialogue on what measures FDA believes are appropriate. Dr. Selden has already offered the following: first, Dr. Selden will agree to an order precluding the use of any non-public information outside of the SEC v. Selden litigation; second, Dr. Selden will agree to a protocol that limits CRL access to "attorneys' eyes only"; and third, Dr. Selden will agree that if information from the CRLs is referred to (by an expert, for example), such reference will not include the applicant name or product; but rather refer to a numerical identifier (e.g., "CRL #1").

Issue #3: FDA Assertion Of "Deliberative Process" Privilege Over Entire Production

FDA's position:

FDA is not intending to assert the deliberative process privilege over every document responsive to the subpoena. Indeed, Selden correctly asserts that FDA waived its deliberative process privilege with respect to a limited number of documents provided to the SEC in a completely unrelated matter, but the circumstances of that decision differed markedly from those in the present action. For instance, FDA disclosed the documents at issue in that case to the SEC pursuant to FDA regulations that permit the inter-agency sharing of documents. See 21 U.S.C. § 20.85.

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With respect to any assertion of the deliberative process privilege, FDA does not believe that this issue is ripe for decision at this point in the litigation. FDA will not agree to summarily waive the deliberative process privilege before the agency has had a chance to assert the privilege in regards to specific documents and provide the Court with the reasoning for the assertion on a privilege log. FDA believes, however, and has consistently maintained, that Dr. Selden's requests seek "disclosure of information that is or contains . . . pre-decisional, and/or agency deliberative process information that is protected from disclosure under the applicable laws, regulations, or privileges." See FDA November 9, 2005 Letter (Attached to Selden's Motion to Compel Memo as Attachment D). A consistent policy of withholding information subject to the deliberative process privilege encourages full and frank discussion among FDA decisionmakers. See 21 C.F.R. § 20.62 (permitting intra-agency writings to be withheld from public disclosure); see also Dep't of Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8-9 (2001) ("The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance 'the quality of agency decisions,' by protecting open and frank discussion among those who make them within the Government.").

Moreover, FDA's decision to withhold privileged information in the present litigation must be analyzed anew, within the confines of the present action. See In re Sealed Case, 121 F.3d 729, 737-738 (D.C. Cir. 1997) ("Each time the deliberative process privilege is asserted the district court must undertake a fresh balancing of the competing interests, taking into account factors such as the relevance of the evidence, the availability of other evidence, the seriousness of the litigation, the role of the government, and the possibility of future timidity by government employees.") (internal citation and quotation marks omitted). The Court's failure to perform a

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"fresh" review of FDA's assertion of the deliberative process privilege would not only negatively impact frank discussions among agency employees, but would also be a strong disincentive for the agency to ever agree to a waiver of the privilege, regardless of the circumstances. Because FDA has not to date asserted the deliberative process privilege in a concrete setting, the issue is not ripe for judicial consideration.

Dr. Selden's Position:

Until very recently, FDA stated that it was contemplating a waiver of the "deliberative process" privilege in this action as it did in the virtually identical SEC v. Biopure action. However, it now says it will not waive the privilege, but that it is premature to discuss its decision in court. FDA's denial of Dr. Selden's request is manifestly ripe for the Court's decision. For several reasons, FDA's decision is both arbitrary and unreasonable.

First, as recently as June 28, 2006, the FDA agreed to waive the privilege, in its entirety, in a virtually identical pending litigation in the District of Massachusetts also brought by the SEC and involving the same regulatory branch of FDA. See SEC v. Biopure Corp., et al., Civ. No. 05-11853-PBS (D. Mass., filed Sept. 15, 2005). There is no sound basis for denying Dr. Selden the same. For example, FDA's only stated reason for asserting the privilege in this case in contrast to Biopure is that the Biopure request came under 21 C.F.R. § 20.85, which provides for the inter-agency sharing of information. See FDA's Position, above. However, both FDA and the SEC have already agreed to use § 20.85 in this case, the same procedure used in Biopure, to request this information from FDA, thus rendering FDA's sole distinction non-existent.

Second, the FDA's only stated justification for asserting the privilege -- that it would "negatively impact frank discussions among agency employees" -- is inapplicable in this case

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because Dr. Selden is not seeking to disclose FDA information to the public, and is willing to agree to a protective order that expressly precludes it.

Third, the effect of the FDA's position would be to eviscerate perhaps the most important reason the subpoenas were issued in the first place; namely, to obtain an understanding of the FDA's own reactions and interpretations of its discussions with the company, Dr. Selden, and the product application.

Issue #4: Depositions of FDA employees

FDA's position:

The subpoenas served upon FDA by Dr. Selden in the present action also requested the depositional testimony of the FDA and the CBER records custodians. Dr. Selden has informed FDA that he seeks such testimony in order to authenticate the records produced by FDA pursuant to these subpoenas. In lieu of these depositions, FDA proposes to authenticate its records via Rule 902 of the Federal Rules of Evidence, consistent with FDA's standard practice when providing documents for use in third-party litigation. see 21 C.F.R. § 20.3 (providing for the certification and authentication of FDA records).

Dr. Selden now seeks to impermissibly expand the present action to encompass his demands for the testimony of four FDA scientists. Such testimony was requested by Dr. Selden pursuant to FDA's Touhy regulations in a letter dated March 29, 2006, See 21 C.F.R. § 20.1, well after the instant litigation was begun. Thus, this request is not part of the current case. After carefully considering this request, FDA permitted Dr. Selden to obtain the testimony of Dr. Walton, the FDA scientist who was previously deposed by the SEC. See FDA Letter dated June 30, 2006. FDA refused to grant Dr. Selden's request for the testimony of the three remaining

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scientists, citing, among other concerns, "FDA's limited resources and the vast number of requests the agency receives for its personnel to testify."

As this Court has already acknowledged, these "subpoenas for testimony are not at issue here." Memorandum Opinion, Aug. 16, 2006, p.3 n.2. FDA's response to Dr. Selden's request for testimony pursuant to FDA's Touhy regulations may only be challenged by Dr. Selden under an arbitrary and capricious standard of review in an action under the Administrative Procedure Act ("APA"). Far from being a "meaningless gesture" as Dr. Selden contends below, such a requirement is well established by the longstanding precedent of this Circuit. See Houston Bus. Journal, Inc. v. Office of the Comptroller, 86 F.3d 1208, 1212 n.4 (D.C. Cir. 1996) (directing third-party litigant to "proceed under the APA, and the federal court will review the agency's decision not to permit its employee to testify under an 'arbitrary and capricious' standard").

Dr. Selden's Position:

Referenced by the Court in its Aug. 16, 2006 Memorandum Opinion (see p. 3 n.2), the testimony of FDA employees Karen Weiss, Duane Rieves and James Kaiser -- which Dr. Selden requested pursuant to FDA's "Touhy" regulations -- are central to his defense and he objects to FDA's refusal to make them available.

The only stated basis for FDA's denial of the testimony is that it would be "duplicative" of Dr. Walton. (FDA's reference above to "other concerns" having been identified in the letter is misleading. The letter specifically stated that it was denying Dr. Selden's request on the basis of the supposed "duplicative" nature of the testimony.) FDA's position is demonstrably false, as Dr. Selden has already communicated to FDA.

Further, with respect to any burden on FDA, Dr. Selden is willing to conduct the depositions during off hours and at any location. A similar procedure was approved by the Court

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for FDA depositions in In re: Vioxx Products Liability Litig., No. MDL 1657, 2006 WL 784878, *12 (E.D. La. Mar. 15, 2006).

Finally, FDA's suggestion of Dr. Selden bringing a separate APA action for relief is, with all due respect, a meaningless gesture under these particular circumstances; where there is an ongoing enforcement action brought by the SEC with the assistance of FDA (including the FDA's permission of "off the record" interviews by SEC of several FDA employees), and is now heading for trial.

Issue #5: Payment of costs for production of FDA documents

FDA's position:

FDA intends to renew its request that Selden be responsible for the significant costs associated with responding to his voluminous subpoena requests, which FDA estimates will require it to dedicate thousands of staff hours in order to produce over 120,000 pages of responsive documents. See Fed. R. Civ. P. 45(c)(2)(B) ("[A]n order to compel production shall protect any person who is not a party . . . from significant expense resulting from the inspection and copying command."). In Northrop Corp. v. McDonnell Douglas Corp, the D.C. Circuit instructed courts to "fully recognize the burden of imposing on a non-party the effort and expense of discovery, particularly when the expense will be borne by the taxpayers." 751 F.2d 395, 407 (D.C. Cir. 1984); see also Linder v. Calero-Portocarrero, 251 F.3d 178, 182 (D.C. Cir. 2001) (concluding that "fee shifting was mandatory" under Rule 45 and requiring the requestor to bear all of the government's nearly $200,000 in costs).

If Dr. Selden's production was being conducted in response to a FOIA request rather than pursuant to a subpoena, the search and review charges would be $40.00 per hour for mid-grade employees, and duplication costs would be $0.10 per page based on the current fee schedule.

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See 21 C.F.R. § 20.45. Based on an estimated volume of up to 120,375 pages of documents and the assignment of three full-time, mid-grade employees for 6 hours per day for twenty-two months, the duplication costs would be approximately $12,000 and the search and review charges would be approximately $317,000.

Dr. Selden's Position:

Dr. Selden, a private citizen, is being accused of fraud by the federal government in an enforcement action that almost certainly would not have been brought without the assistance of FDA. The FDA's involvement in this case stems back to the earliest phases of the SEC's investigation. Having supplied critical assistance to the SEC, including "off the record" interviews of key witnesses, the FDA now wants Dr. Selden to bear the burden and expense of seeking discovery from the very agency that is behind the lawsuit against him. This is unfair and inappropriate.

EXHIBIT 5

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No.
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	Related To: S.E.C. v. Richard F. Selden, Civil Action No. 05-11805-NMG
Defendants.	:	06 CA 11807 NMG

PLAINTIFF'S STATEMENT CONCERNING
THE COURT'S JURISDICTION IN THIS MATTER

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Counsel for Plaintiff
Richard F. Selden

Dated: October 5, 2006

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Preliminary Statement

Plaintiff Richard F. Selden ("Dr. Selden") has filed an action today seeking declaratory and injunctive relief against the United States Food and Drug Administration ("FDA") and Andrew C. von Eschenbach, in his official capacity as acting commissioner of the FDA, to obtain the FDA's meaningful compliance with a final ruling of the United States District Court for the District of Columbia in S.E.C. v. Richard F. Selden, No. 1:05-mc-00476-RMU (D.D.C., Aug. 16, 2006) (the "D.C. Order"),[1] which granted Dr. Selden's motion to compel and ordered the FDA to produce documents in response to two federal subpoenas issued by Dr. Selden on October 28, 2005.

At the status conference before this Court on September 28, 2006, the Court requested briefing on the question of its jurisdiction in connection with this action.

STATEMENT OF JURISDICTION

I. SUBJECT MATTER JURISDICTION

The Court's subject matter jurisdiction is based on four separate federal questions.

A. Federal Question: Administrative Procedure Act

Dr. Selden's first claim for relief is based on the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-06. The APA creates a private right of action for injunctive relief in federal court against the United States and its agencies and officers: "An action in a court of the United States seeking relief other than money damages . . . shall not be dismissed nor relief therein be denied on the ground that it is against the United States."

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[1] A copy of the D.C. Order is attached at Tab A to Plaintiff's Motion For Order To Show Cause And Preliminary Injunction, also filed today.

5 U.S.C. § 702. Because an APA claim arises under the laws of the United States, there is subject matter jurisdiction based on federal question jurisdiction under 28 U.S.C. § 1331. See also Conservation Law Found., Inc. v. Busey, 79 F.3d 1250, 1260-61 (1st Cir. 1996); Califano v. Sanders, 430 U.S. 99, 104-07 (1977).

The APA authorizes federal courts both to "compel agency action unlawfully withheld or unreasonably delayed" and to "hold unlawful and set aside agency action, findings, and conclusions" that are, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706 (emphasis added). To sustain the latter type of claim, there must be "final agency action," id. § 704, which is defined to include the "failure to act," 5 U.S.C. § 551(13). In this case, the FDA's refusal to comply in a timely manner with the D.C. Order constitutes action withheld and unreasonably delayed as well as a failure to act, all of which is now reviewable under the APA. See Complaint, Selden v. FDA ("FDA Compl.") ¶¶ 20-26.

B. Federal Question: Mandamus Act

Under the Mandamus Act, "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361. Dr. Selden alleges that the FDA owes a clear duty to him under the D.C. Order and has failed in its performance of that duty. FDA Compl. ¶¶ 27-33.[2]

[2] At least two courts have found that the All Writs Act, 28 U.S.C. § 1651(a), also gives district courts the power to compel agency action. See Natural Res. Def. Council, Inc. v. Jamison, 815 F. Supp. 454, 464 n.50 (D.D.C. 1992); Moss v. Arnold, 654 F. Supp. 19, 22 (S.D. Ohio 1986).

C. Federal Question: Freedom Of Information Act

Dr. Selden's third claim for relief is based on the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, et seq. The statute's basic purpose is "to ensure an informed citizenry, vital to the functioning of a democratic society, or, stated more specifically, to open agency action to the light of public scrutiny . . . The policy underlying FOIA is thus one of broad disclosure." Church of Scientology Int'l v. U.S. Dept. of Justice, 30 F.3d 224, 228 (1st Cir. 1994) (citations and internal quotations omitted). With respect to subject matter jurisdiction, as stated by the Supreme Court: "The FOIA confers jurisdiction on the district courts 'to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld.' Under this provision, 'federal jurisdiction is dependent on a showing that an agency has (1) improperly (2) withheld (3) agency records.'" U.S. Dept. of Justice v. Tax Analysts, 492 U.S. 136, 142 (1989) (citations omitted). That is precisely what Dr. Selden alleges here. FDA Compl. ¶¶ 34-41.

D. Federal Question: "Non-Statutory"

Dr. Selden's fourth claim seeks injunctive relief pursuant to the Declaratory Judgment Act. 28 U.S.C. § 2201. FDA Compl. ¶¶ 42-46. The First Circuit has held that this "non-statutory" cause of action also confers federal subject matter jurisdiction:

> The basic premise behind nonstatutory review is that, even after the passage of the APA, some residuum of power remains with the district court to review agency action that is ultra vires. Such claims usually take the form of a suit seeking an injunction, often accompanied by a request for relief under the Declaratory Judgment Act, 28 U.S.C. § 2201. The nonstatutory review action finds its jurisdictional toehold in the general grant of federal-question jurisdiction of 28 U.S.C. § 1331.

Rhode Island Dept. of Envtl. Mgmt. v. U.S., 304 F.3d 31, 42 (1st Cir. 2002) (citations omitted).

II. "PERSONAL" JURISDICTION AND VENUE

"Personal" jurisdiction of the federal courts over the United States, its agencies and its officers is determined exclusively by Congress. Minnesota v. U.S., 305 U.S. 382, 388 (1939) ("[I]t rests with Congress to determine not only whether the United States may be sued, but in what courts the suit may be brought."). In Section 1391 of Title 28, Congress specifically provided that:

> A civil action in which a defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, or the United States, may, except as otherwise provided by law, be brought in any judicial district in which (1) a defendant in the action resides, (2) a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (3) the plaintiff resides if no real property is involved in the action.

28 U.S.C. § 1391(e) (emphasis added). Similarly, with respect to FOIA actions: "On complaint, the district court of the United States in the district in which the complainant resides . . . has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant." 5 U.S.C. § 552(a)(4)(B) (emphasis added).

Finally, with respect to service, § 1391 states that "[t]he summons and complaint in such an action shall be served as provided by the Federal Rules of Civil Procedure," id., and Rule 4 provides for nationwide service of process on the United States, its agencies and officers, Fed. R. Civ. P. 4(i).

Conclusion

For all of the foregoing reasons as well as those reasons contained in Dr. Selden's other supporting papers, this Court should grant Plaintiff's Motion For Order To Show Cause And Preliminary Injunction and direct entry of an order consistent with the relief requested therein.

Dated: October 5, 2006
Boston, Massachusetts

Respectfully submitted,

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EXHIBIT 6

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No.
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	Related To: S.E.C. v. Richard F. Selden, Civil Action No. 05-11805-NMG
Defendants.	:	

NOTICE OF FILING WITH CLERK'S OFFICE

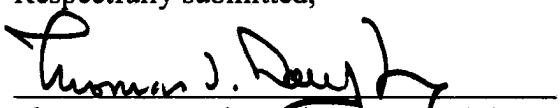
Notice is hereby given that the documents, exhibits or attachments listed below have been manually filed with the Court and are available in paper form only:

- Affidavit Of Justin J. Daniels In Support Of Plaintiff's Motion For Order To Show Cause And Preliminary Injunction

The original documents are maintained in the case file in the Clerk's Office.

Dated: October 5, 2006
Boston, Massachusetts

Respectfully submitted,



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